

EPA Jacket 86230-2

Vol.2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 7, 2015

James Messina
Loradochem, Inc.
1021 Stony Hill Road, Suite 200
Yardley, PA 19067

Subject: Notice of Extension of Conditional Registration until **June 26, 2017**
Product Names:
LC-2010-1 FIPRONIL FOR CATS
LC-2010-2 FIPRONIL FOR DOGS
EPA Registration Numbers: 86230-1;86230-2
Application Date: August 6, 2015
Decision Numbers: 507784; 507785

Dear Mr. Messina:

This letter is in reference to your request to extend the conditional, time-limited registration for the above-referenced registration. The above-referenced registration contains conditions calling for the registration to expire after two years. Additionally, your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information for the above-referenced registration.

The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is therefore granting the request to extend the two-year time-limited registration restriction. As such, the following change is being made to the terms and conditions for the product listed above:

- The two-year time-limited registration restriction has been extended. The new expiration date for the registration listed above is **June 26, 2017**.

Please note that the product is still subject to all other previously required conditions of registration. If your company wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for the product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you remember, the Agency included this time limitation as a condition of registration for your product to allow for the post-market surveillance¹ of the product. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g., tables, charts, information on stewardship activities, etc.):

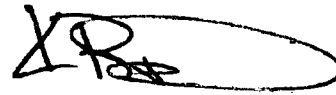
¹ <http://www.epa.gov/pesticides/health/spot-on-meetings.html>

- A summary and analysis of the incidents received associated with the product, including information on the following:
 - A comprehensive analysis of incident rates per doses distributed;
 - An analysis of historical incident trends since the products' release into the marketplace;
 - An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If the product is also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day fast-track submissions, as the Agency requires time to fully evaluate the information provided. After receiving these submissions, the Agency will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

If you have any questions, you may contact Maggie Rudick at (703) 347-0257 or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Note to File

Date: August 7, 2015

Registration Number: 86230-1 and 86230-2

Decision Number: 507184; 507785

PM/RM Name: Maggie Rudick, IVB1 Team 3

Background: The time limited registration expired June 26, 2015. The company requested extension of their registration on August 6, 2015.

Decision: After discussions with Dan Rosenblatt, it was decided that we would approve the time limited extension request for Exponent this one time. The company was made aware that this would not happen in the future.

August 6, 2015

Kable Bo Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**Subject: Two-Year Extension of Time Limited Registration for
LC-2010-1 Fipronil For Cats, EPA Reg. No. 86230-1
LC-2010-2 Fipronil For Dogs, EPA Reg. No. 86230-2**

Dear Mr. Davis:

Exponent, Inc. is submitting a request to extend the two-year time limited registrations for the subject end use products for an additional two years on behalf of its client, Loradochem, Inc., 1020 Stony Hill Road, Suite 200, Yardley PA 19067 (EPA Co. No. 86230) .

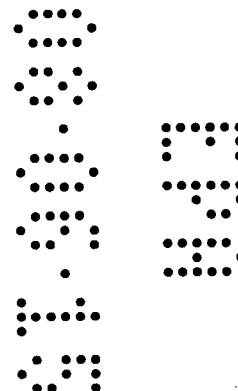
If you have any questions, please contact me at 202-772-4932 or jmessina@exponent.com.

Sincerely,



James Messina
Authorized Representative of
Loradochem, Inc.

cc: John Caldwell, Loradochem, Inc.



EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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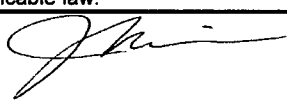
Application for Pesticide - Section I			
1. Company/Product Number 86230-2	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Loradochem, Inc./ LC-2010-2 Fipronil For Dogs	5. PM# 3		
5. Name and Address of Applicant (Include ZIP Code) Loradochem, Inc 1020 Stony Hill Road, Suite 200 Yardley PA 19067 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II	
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for Two-Year Extension of Time Limited Registration

Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Can <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV		
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James Messina	Title Authorized Representative	Telephone No. (Include Area Code) 202-772-4932
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: 	3. Title Authorized Representative	
4. Typed Name: James Messina	5. Date: August 5, 2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 20, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JAMES MESSINA
EXPONENT, INC., AGENT FOR
LORADOCHEM, INC.
1150 CONNECTICUT AVE., SUITE 1100
WASHINGTON, DC 20036

Dear Registrant:

Your request for a change in your Official EPA Company Name and Address record has been completed. For your confirmation the Official EPA Company Name and Address record for EPA Company Number: **86230** is listed below.

MR. JOHN W. CALDWELL
LORADOCHEM, INC.
1020 STONY HILL ROAD, SUITE 200
YEARDLEY, PA 19067

Agent Address:

MR. JAMES MESSINA
EXPONENT, INC., AGENT FOR
LORADOCHEM, INC.
1150 CONNECTICUT AVE., SUITE 1100
WASHINGTON, DC 20036

Any future changes in company name and/or address or changes in designation/withdrawal of authorized agent should be directed to the following address. It can also be faxed to (703) 305-7670.

Document Processing Desk (COADR)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

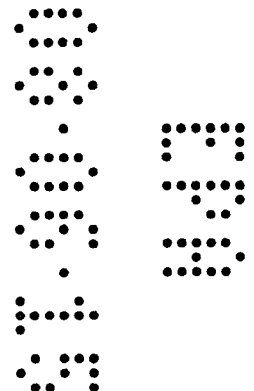
If you have any questions, please call me at (703) 308-8114.

Sincerely,

Louis Vaughn

Louis Vaughn
Office of Pesticide Programs

RE: 86230_COADR_02_20_2015





February 10, 2015

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

To whom it may concern:

Please be advised that Velcera, Inc. (Company number 88146), its affiliated companies, LoradoChem, Inc. (Company number 86230), and FidoPharm, Inc. (Company number 85495) hereby appoints:

Exponent, Inc.
1150 Connecticut Avenue
NW, Suite 1100
Washington DC, 20036

as their Agent of Record to address all registration matters on their behalf before the United States Environmental Protection Agency in replacement of:

Dr. Iain Weatherston
J&T Associates LLC
4061 North 156th Street
Goodyear, AZ 85395

This appointment and authorization for Registration Agent will remain in effect until revoked in writing by Company Official or Authorized Agent.

Sincerely,

A handwritten signature in dark ink that reads "Prince M. Bamaze". The signature is written in a cursive, flowing style.

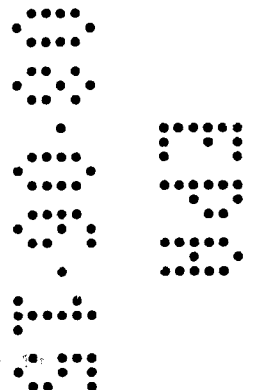
Prince M. Bamaze

Regulatory Affairs

Velcera, Inc.

cc: Exponent, Inc.

Velcera, Inc.
10077 South 134th Street • Omaha, Nebraska 68138-3710 USA
Phone: 402-938-7065 • Fax: 402-938-7165



Vaughn, Louis

From: Vaughn, Louis
Sent: Friday, February 20, 2015 6:04 PM
To: 'James Messina'; 'bpolakoff@exponent.com'
Cc: 'iweatherston@cox.net'
Subject: COADR 86230
Attachments: L_86230_COADR_02_20_2015.pdf; Company_Transfer_Sample_Agreement_2015.rtf

Attached, is the requested Agent Change for EPA Company **86230**. This agent authorization came on VELCERA, INC. letterhead. Technically a change of agent is supposed to be on Company Letterhead from the "affected" company (not an "affiliated" company). However, since this company and its "affiliated companies" are obviously at the same address, and have the same agent, I am making this one-time exception.

NOTE: Since Perrigo acquired 100% of LoradoChem, Inc., you may wish to record the Company Transfer with us (before institutional knowledge of the event is lost).

Attachments.

Best regards.

For Change of Address or Agent:

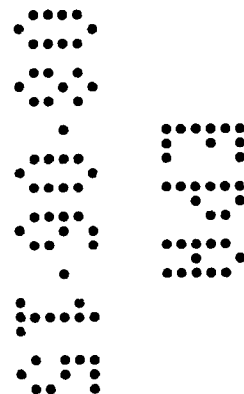
<http://www.epa.gov/pesticides/registrationkit/change-company-name-address-agent.pdf>

For Product Transfers, Data Transfers or Company Numbers Transfers:

<http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>

For Other Information: <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual>

Louis Vaughn, Information Management Specialist
U.S. Environmental Protection Agency
OCSP/OPP/ITRMD/ISB
(703)308-8114
vaughn.louis@epa.gov





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

August 17, 2015

Mr. Kelly Hoskins
LoredoChem, Inc.
1020 Stoney Hill Road, Suite 200
Yeadley, PA 19067

Subject: Label Amendment – Additional marking claims; clarification of directions for use
Product Name: LC-2010-2 FIPRONIL FOR DOGS
EPA Registration Number: 86230-2
Application Date: March 3, 2015
Decision Number: 502168

Dear Mr. Hoskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

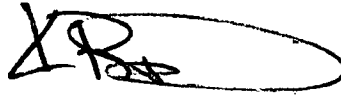
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 86230-2
Decision No. 502168

with FIFRA section 6. If you have any questions, please contact me by phone at (703) 306-0415,
or via email at davis.kable@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

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EPA SAL 5 Aug 2014

FRONT PANEL

DOG SQUEEZE ON FIPRONIL

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.] “Pipette/Vial/Tube/Applicator” can be used interchangeably

LC-2010-2 FIPRONIL FOR DOGS

[ABNs:]

[PetArmor™ for Dogs]

[TrustGard™ for Dogs]

[Velcera® Fipronil for Dogs]

[Sergeant's® Pet Armor for Dogs]

[Pet Armor for Dogs]

[[1]][2][3][4][5][6][12][24](Drawing of
pipette/vial/tube/applicator)]
[1.5cm x 1.5cm on final or as indicated]



[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

[Only use on dogs 23-44 lbs. 8 weeks or older]

[Only use on dogs 45-88 lbs.]

[Only use on dogs 89-132 lbs.]

[Picture of a dog that is the appropriate for the size of dog for each weight range]

{box only designates Vet Only language}

{SUBLABEL: FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION}

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels.
Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

[Ticks]

[Kills ticks, including ticks that may transmit Lyme Disease]

[Mosquitoes]

[Kills mosquitoes]

[Multiple Infestations]

[Kills fleas, ticks, chewing lice & Mosquitoes]

[All Others]

[For Dogs and puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4 to 22 lbs.], [5 to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]

[Fast Acting] [Long Lasting]

[Easy to Use [Application]]

[[Easy to use] [applicator]]

ACCEPTED

08/17/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 86230-2

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

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[Easy-to-use topical application]
[Apply monthly]
[Once a month treatment]
[For year-round protection, apply [Brand name][this product] monthly]
[(ICON Showing [4 Week] [1 month] [30 day] Protection)]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[[One][1][Two][2][Three] [3][4][Four][5][Five] [Six][6][Twelve][12][Twenty-Four][24]]Applications] and/or
[1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 Month
Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week
Supply][20 week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Waterproof]
[Effective even after bathing]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]
[[Free] Calendar Stickers Inside!]
[Monthly application reminder inside]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][clip] [inside]]
[Fipronil (9.7%)]
[Contains the same active ingredient used in [Fipaira for Dogs (or any approved ABN)].*]
[Compare to [Fipaira for Dogs (or any approved ABN)], contains the same active ingredient.*]
[Compare to [Fipaira for Dogs (or any approved ABN)], contains the same active ingredient fipronil.*]
[[Brand Name] [products] [This product] contains(s) fipronil, the same active ingredient used in [Fipaira for
Dogs (or any approved ABN)].*]
[[Brand Name] [products] [This product] contains(s) fipronil, compared to the same active ingredient used in
[Fipaira for Dogs (or any approved ABN)].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers
of [Fipaira for Dogs (or any approved ABN)].]
[[Brand Name][This product][Fipaira] is a trademark of [Merial®] [Company name].]
[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]
[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]
[Stops existing infestation and prevents establishment of additional infestation of listed pests]
[[S][Small] (5 to 22 lbs.) [[M][Medium] (23-44lbs.)] [[L][Large] (45-88 lbs.)] [[XL][Extra Large] (89-132 lbs.)]
[[For Small Dogs 5-22 lbs.] [For Medium Dogs 23-44 lbs.] [For Large Dogs 45-88 lbs.] [For Extra Large Dogs
89-132 lbs.]]
[Direct to skin [tube][vial][applicator][pipette]]
[Direct to dog's skin [applicator][tube][vial][pipette]]
[Easy to Use] [tube][vial][applicator][pipette]]
[Clean cut [open] [tube][vial][applicator][pipette]]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette][!]]
[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]
[Save Now!]
[Value Size]
[Club Size]
[Bonus Size]
[Club Pack]
[Great Value]
[Better Value]
[Bonus Pack]
[(x) + (x) bonus pack!]

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

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[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

[(x) Dose(s) Free!]

[(x) Day(s) (Free)!]

[(x) Month(s) Free!]

[(x) Day(s) of treatment- Free!]

[(x) Tube(s) Free!]

[(x) Applicator(s) Free!]

[(x) Application(s) Free!]

[Clip, Part, Squeeze]

[Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin]

[Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **squeeze** directly onto the skin]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT:

Fipronil..... 9.70%

OTHER INGREDIENTS: 90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Insert] [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl. oz. [Y – 0.0xx fl oz (x ml) [tube] [vial] [applicator] [pipette]]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

OR {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]]

[Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty 160]

[0.023 fl oz (0.67 mL)][0.045 fl oz (1.34 mL)][0.091 fl oz (2.68 mL)][0.136 fl oz (4.02 mL)]

[tube] [vial] [applicator] [pipette]s]

{END - FRONT PANEL}

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

Version 15.1a
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BACK/SIDE PANEL

DOG SQUEEZE ON FIPRONIL

LC-2010-2 [or other approved alternate brand name] For Dogs

[Brand Name][This product] acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes

[ONLY on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older].

Or ...[ONLY on dogs weighing 23-44 lbs. and 8 weeks or older].

Or ...[ONLY on dogs weighing 45-88 lbs.]

Or ...[ONLY on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one tube/vial/pipette per dog per month.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply [Brand Name][This product] ONLY to dogs and puppies aged 8 weeks or older and 5–22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes.

{Outer Packaging} {Drawing of pipette/vial/tube/applicator} {Drawing of treating animal}

How to apply:

1. Remove product {pipette/vial/tube/applicator} from the package
2. [Separate one {pipette/vial/tube/applicator} from the others.] Hold the {pipette/vial/tube/applicator} with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the {pipette/vial/tube/applicator} behind the neck and between the shoulders. Ensure that the entire application of [Brand Name][This product] is contained in a single spot on the dog's skin. Be sure to squeeze the {pipette/vial/tube/applicator} thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one {pipette/vial/tube/applicator} during each application. Do not touch the area where the application was made until it is dry.

[Brand Name][This product] also aids in the control of sarcoptic mange infestations.

FREQUENCY OF APPLICATION

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply [Brand Name][This product] for thirty (30) days.

Sergeant's Master Label

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Information in [] is optional.

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Side Effects: Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

{1.5 cm x 1.5 cm on final or as indicated}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

©2013 LoradoChem, Inc. All rights reserved. [Made in USA]
(Drawing of telephone receiver) Questions? Comments? 1-888-908-TICK

LoradoChem, Inc.
10077 South 134th Street
Omaha, NE 68138 USA

[BAR CODE AREA][Lot code]
EPA Reg. No. 86230-2
EPA Est. No. [XXX-XX-XXX]

{END - BACK/SIDE PANEL}

TUBE/VIAL LABEL

{Front Label}

{Icon as indicated}

DOG SQUEEZE ON FIPRONIL

{Back Label}

{Brand Name} For Dogs [X-Y] lbs ≥8 wks
Fipronil 9.7%
0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)
0.136 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions
before using. Use scissors to open.
EPA REG. No. 86230-2 {label code}

{EPA REG No may be on either the front or back label}

{END - TUBE/VIAL LABEL}

PACKAGE INSERT

DOG SQUEEZE ON FIPRONIL

LC-2010-2 [or other approved alternate brand name] For Dogs

Only for use on dogs and puppies 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]
[Brand Name][This product] is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENTS:90.30%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

[Brand Name][This product] acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, [Brand Name][This product] can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. [Brand Name][This product] also aids in the control of sarcoptic mange infestations.

Specifically, [Brand Name][This product] kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

Version 15.1a
Page 6 of 8

EPA No. 86230-2
EPA SAL 5 Aug 2014

dermatitis;

- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease);
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

[Brand Name][This product] contains the active ingredient fipronil.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply [Brand Name][This product] ONLY to dogs and puppies aged 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

{Drawing of a pipette/vial/tube} {Drawing of treating animal}

1. Remove product {pipette/vial/tube/applicator} from the package
2. [Separate one {pipette/vial/tube/applicator} from the others.] Hold the {pipette/vial/tube/applicator} with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the {pipette/vial/tube/applicator} behind the neck and between the shoulders. Ensure that the entire application of [Brand Name][This product] is contained in a single spot on the dog's skin. Be sure to squeeze the {pipette/vial/tube/applicator} thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one {pipette/vial/tube/applicator} during each application. Do not touch the area where the application was made until it is dry.

[Brand Name][This product] also aids in the control of sarcoptic mange infestations.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply [Brand Name][This product] for thirty (30) days.

Side Effects: Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

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{1.5 cm x 1.5 cm on final or as indicated}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

OR {box only designates Vet Only language}

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

Version 15.1a
Page 8 of 8

EPA No. 86230-2
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Application Options for Different Sizes of Dogs

[Brand Name][This product] comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

* 5 to 22 lbs.

* 23 to 44 lbs.

* 45 to 88 lbs.

* 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] [LoradoChem, Inc.] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

(Drawing of telephone receiver) Questions? Comments? 1-888-908-TICK [Made in USA]

[Distributed by:] [Manufactured by:]
LoradoChem, Inc.
10077 South 134th Street
Omaha, NE 68138 USA

[BAR CODE AREA][Lot code]
EPA Reg. No. 86230-2
EPA Est. No. [XXX-XX-XXX]

©2013 LoradoChem, Inc. All rights reserved.

{END - Package Insert}

Sergeant's Master Label

24 Feb 2015 Amendment
Information in [] is optional.

Version 15.1a
Page 9 of 8

EPA No. 86230-2
EPA SAL 5 Aug 2014

SUB LABEL – STICKERS FOR RE-APPLICATION REMINDERS DOG SQUEEZE ON FIPRONIL

LC-2010-2

[or other approved alternate brand name]

**For Dogs
Care Card**

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

{Picture of a Dog}

Month 1, Month 2, Month 3, Month 4, Month 5, Month 6

Drawing of paw

Date of Application

Place sticker on your calendar or refrigerator to remind yourself to apply [Brand Name][This product] to your dog

Pet's Name: lbs.

{END – SUB LABEL - STICKERS}

Chao, Julie

Subject: FW: 86230-1 and 86230-2: Pending Label Amendments
Attachments: 86230-1 V15.1a AMND Submission 7Aug15 Approved (Pending) Clean.pdf; 86230-2 V15.1a AMND Submission 7Aug15 Approved (Pending) Clean.pdf

From: Kelly Hoskins [mailto:Kelly.Hoskins@perrigo.com]
Sent: Monday, August 10, 2015 11:35 AM
To: Chao, Julie
Cc: Prince Bamaze
Subject: RE: 86230-1 and 86230-2: Pending Label Amendments

Julie,
Here are the clean pdfs, please let me know if you have any questions.

Please note the change in my email address as Sergeant's makes the transition to Sergeant's Pet Care Products, Inc. D/B/A Perrigo Animal Health.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: kelly.hoskins@perrigo.com | sergeants.com



From: Chao, Julie [mailto:Chao.Julie@epa.gov]
Sent: Monday, August 10, 2015 5:59 AM
To: Kelly Hoskins
Cc: Prince Bamaze
Subject: RE: 86230-1 and 86230-2: Pending Label Amendments

Hi Kelly,

These look good. Can you submit clean copies? (PDFs preferred).

Thanks!
Julie

From: Kelly Hoskins [mailto:Kelly.Hoskins@perrigo.com]
Sent: Friday, August 07, 2015 7:08 PM
To: Chao, Julie
Cc: Prince Bamaze
Subject: RE: 86230-1 and 86230-2: Pending Label Amendments

Julie,
Congratulations on the new PM position.

If these need to go to another person please let me know.

I have updated the labels to the Fip only products using the same color scheme, yellow existing, green bulk/vet pack, blue for any new changes.

The blue changes are mostly marketing but there are a few other areas that follow along the mitigation changes, but all follow the recently approved language.

I have removed the #1 Vet claims and I tried to leave as much as possible to avoid redoing the whole label over. I did change the order of the First Aid and Precautionary Statements per the original request.

Please let me know if you have any questions.

Please note the change in my email address as Sergeant's makes the transition to Sergeant's Pet Care Products, Inc. D/B/A Perrigo Animal Health.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.

A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710

T: 402.938.7079

F: 402.938.7179

E: kelly.hoskins@perrigo.com | sergeants.com



From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]
Sent: Friday, July 24, 2015 1:33 PM
To: Kelly Hoskins
Subject: 86230-1 and 86230-2: Pending Label Amendments

Hi Kelly,

I have the pending label amendments for 86230-1 and 86230-2 that you had been corresponding with Autumn Metzger on. Do you want to go ahead and revise in accordance with the language that we approved for similar products (2517-134, 135, 136, 137)? You can email the revised labels to me.

Thanks!
Julie

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: S. Hill

Date: 3/11/15

PM #: 3

EPA Reg. Number: <u>26230-2</u>		EPA Receipt Date: <u>3/3/15</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	x		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			~
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			
	a) Selective Method?			~
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)	x		
	a) Electronic Label submitted?		x	
Comments:				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 9, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JAMES MESSINA
EXPONENT, INC.
LORADOCHEM, INC.
1150 CONNECTICUT AVE., SUITE 1100
WASHINGTON, DC 20036-

PRODUCT NAME: LC-2010-2 FIPRONIL FOR DOGS
COMPANY NAME: LORADOCHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86230-2
EPA RECEIPT DATE: 03/03/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 306-0415.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J. S.", written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{965106ä~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 3

Receipt No.

S- 965106

EPA File Symbol/Reg. No.

86230-2

Pin-Punch Date:

3/3/2015

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 3-6-15

Remarks:

EPA
 United States
Environmental Protection Agency
 Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Kable Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoredoChem Inc. / LC-2010-2 Fipronil for Dogs	5. PM # 3	
5. Name and Address of Applicant (Include ZIP Code) LoredoChem Inc. 1020 Stoney Hill Road, Suite 200, Yeardley PA, 19067 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: _____

Section II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Non-PRIA label amendment. Please see cover letter for details.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	<input type="checkbox"/> Plastic	
*Certification must be submitted				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) Plastic Bag	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Can <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly R. Hoskins	Title Manager of Regulatory Affairs, Sergeant's Pet Care Products, Inc.	Telephone No. (Include Area Code) 402-938-7079
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>	3. Title Manager of Regulatory Affairs, Sergeant's Pet Care Products, Inc.	
4. Typed Name: Kelly R. Hoskins	5. Date: March 3, 2015	



March 3, 2015

Kable Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (AMEND)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Amendment (Revised Label) for
LC-2010-2 Fipronil for Dogs,
EPA Registration Number 86230-2

Dear Mr. Davis:

On behalf of LoredoChem Inc. (LoredoChem, 1020 Stoney Hill Road, Suite 200, Yeardley PA, 19067, EPA Company Number 86230), Velcera, Inc. is submitting an application for pesticide amendment to revise the master label for the end-use product, LC-2010-2 Fipronil for Dogs (EPA Registration Number 86230-2). The following items are enclosed in support of this non-PRIA3 label amendment action:

- Application for Pesticide Amendment (EPA Form 8570-1); and
- Product master label v15.1 (5 copies, one copy with all changes highlighted)
- EPA Stamped Letter/Label dated August 5, 2014 (for Agency's reference).

LoredoChem is revising the master label to add multiple, new optional active ingredient reference statements. Also, text has been added to clarify optional language, location of the language on the packaging and interchangeability of pipette/vial/tube/applicator. These revisions don't necessitate any data review. All changes from the current EPA label dated August 5, 2014 are highlighted on one copy of the revised label. Finally, please note that the current label has been reviewed and accepted as meeting the Agency's pet spot-on mitigation measures.

Please note that Perrigo Company PLC has acquired Sergeant's Pet Care Products Inc. assets, which includes Velcera, Inc. the parent company of LoredoChem Inc.

If you have any questions regarding this submission, please contact me at 402-938-7079 or Kelly.Hoskins@perrigo.com.

Sincerely,

A handwritten signature in cursive script that reads "Kelly R. Hoskins".

Kelly R. Hoskins
Manager of Regulatory Affairs,
Sergeant's Pet Care Products, Inc.

Enclosures

DATA EXTRACTION REQUEST

Reg # 86230-2 Decision # 487966

Description: Label Amendment - Fast Track

Material Sent:

☒ Electronic Label/Letter Dated Aug. 5, 2014
(See PPLS for electronic file)

☐ Stamped Label Dated _____ (See jacket)

☐ Notification Dated _____ (See jacket)

☐ New CSF(s) Dated _____ (See jacket)

☐ Other: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carolyn Petrelli

Division: RD

Phone: 347-0439

Date: 8/6/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 5, 2014

Dr. Ian Weatherston, Agent
Loredo Chem Inc.
c/o J&T Associates, LLC
4061 North 156th
Goodyear, AZ 85395

Subject: Label Amendment – Adding and Editing Marketing Claims
Product Name: LC-2010-2 Fipronil for Dogs
EPA Registration Number: 86230-2
Application Date: May 16, 2014
Decision Number: 487966

Dear Dr. Weatherston:

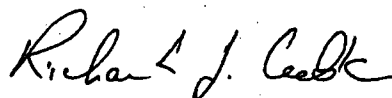
The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval **does not** supersede any of the pet mitigation and enhanced incident reporting requirements outlined in the Agency letters dated January 10, 2011 and June 26, 2013. You are reminded that this registration shall expire on June 26, 2015, unless the Agency receives a formal request to extend the registration for this product.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Page 2 of 2
EPA Reg. No. 86230-2
Decision No. 487966

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at 'petrella.carlyn@epa.gov'.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken". The signature is fluid and cursive, with the first name "Richard" and last name "Gebken" clearly distinguishable.

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: August 5, 2014

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

[] -- alternate verbiage

“Pipette/Vial/Tube/Applicator” can be used interchangeably

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.70%
OTHER INGREDIENTS.....90.30%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2

ACCEPTED

08/05/2014

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 86230-2

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-2

[Alternate Brand Names]

[PetArmor™ for Dogs]

[TrustGard™ for Dogs]

[Velcera® Fipronil for Dogs]

[Sergeant's® Pet Armor for Dogs]

[Pet Armor for Dogs]

FOR DOGS

3 (Drawing of pipette/vial/tube)

[Alternate Packaging]

[6 (Drawing of pipette/vial/tube)]

[1 (Drawing of pipette/vial/tube)]

[2 (Drawing pipette/vial/tube)]

[4 (Drawing of pipette/vial/tube)]

[5 (Drawing of pipette/vial/tube)]

[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

[Pipette[s]/Vial[s]/Tube[s]

- Kills fleas, ticks, chewing lice & Mosquitoes
- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control
- Direct to dog's skin [applicator][tube][vial][pipette]
- Bonus
- Buy "x" get "y" free
- Get "x%" free
- "X%" More Free
- Clip, Part, Squeeze
- [For Small Dogs 5-22 lbs.] [For Medium Dogs 23-44 lbs.] [For Large Dogs 45-88 lbs.] [For Extra Large Dogs 89-132 lbs.]
- [Easy to use][applicator]
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin

- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **squeeze** directly onto the skin
- Clean cut [open][applicator!]
- No mess [open][applicator]]
- Clip-tip design [applicator][!]]
- [Contains the same active ingredient used in FRONTLINE® Top Spot® for Dogs]
- [This product is not manufactured or distributed by [Merial®,] the makers of FRONTLINE® Top Spot ® for Dogs]
- [FRONTLINE®] [Frontline® Top Spot ®] is a registered trademark of Merial®.]
- [[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.70%

OTHER INGREDIENTS.....90.30%

TOTAL.....100.00%

(Picture of dog that is appropriate for the size of dog for each weight range)

KEEP OUT OF REACH OF CHILDREN

(1.5x1.5 cm Cat prohibition Icon)

CAUTION

[Contains 3-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.069 fl.oz.]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.135 fl.oz.]

Or
 [Contains 3-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.273 fl.oz.]
 Or
 [Contains 3-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.408 fl.oz.]
 Or
 [Contains 6-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.138 fl.oz.]
 Or
 [Contains 6-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.270 fl.oz.]
 Or
 [Contains 6-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.546 fl.oz.]
 Or
 [Contains 6-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.816 fl.oz.]
 Or
 [Contains 1-0.023 fl.oz (0.67 mL) pipette]
 Or
 [Contains 1-0.045 fl.oz. (1.34 mL) pipette]
 Or
 [Contains 1-0.091 fl.oz. (2.68 mL) pipette]
 Or
 [Contains 1-0.136 fl.oz (4.02 mL) pipette]
 Or
 [Contains 2-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.046 fl.oz.]
 Or
 [Contains 2-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.090 fl.oz.]
 Or
 [Contains 2-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.182 fl.oz.]
 Or
 [Contains 2-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.272 fl.oz.]
 Or
 [Contains 4-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.092 fl.oz.]
 Or
 [Contains 4-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.180 fl.oz.]
 Or
 [Contains 4-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.364 fl.oz.]
 Or
 [Contains 4-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.544 fl.oz.]
 Or
 [Contains 5-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.115 fl.oz.]
 Or
 [Contains 5-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.225 fl.oz.]
 Or
 [Contains 5-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.455 fl.oz.]
 Or
 [Contains 5-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.680 fl.oz.]
 Or
 [Contains 12-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.276 fl.oz.]

Or
[Contains 12-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.540 fl.oz.]
Or
[Contains 12-0.091 fl.oz. (2.68 mL) pipettes. Net weight 1.092 fl.oz.]
Or
[Contains 12-0.136 fl.oz (4.02 mL) pipettes. Net weight 1.632 fl.oz.]
Or
[Contains 24-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.552 fl.oz.]
Or
[Contains 24-0.045 fl.oz. (1.34 mL) pipettes. Net weight 1.08 fl.oz.]
Or
[Contains 24-0.091 fl.oz. (2.68 mL) pipettes. Net weight 2.184 fl.oz.]
Or
[Contains 24-0.136 fl.oz (4.02 mL) pipettes. Net weight 3.264 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs
LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older]
Or ...[ONLY on dogs weighing 23-44 lbs. and 8 weeks or older].
Or ...[ONLY on dogs weighing 45-88 lbs.]
Or ...[ONLY on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]
Do not use more than one tube/vial/pipette per dog per month.
[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND

ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and 5–22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Remove product tube/vial from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
10077 South 134th Street
Omaha, NE
68138 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

©2013 LoradoChem, Inc. All rights reserved.

(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in USA

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	[2 (Drawing of pipette/vial/tube)]
Or	[4 (Drawing of pipette/vial/tube)]
[Only use on dogs 89-132 lbs.]	[5 (Drawing of pipette/vial/tube)]
	[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	[2,4,5,12, or 24]
Or	
[Only use on dogs 89-132 lbs.]	

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Left side panel of Box]

Lot Number:	3 (Drawing of pipette)
	[6 (Drawing of pipette)]
	[1 (Drawing of pipette)]
	[2,4,5,12,or 24]
	Pipette[s]

Sublabel B: Package Insert

LC-2010-2 [or other approved alternate brand name] For Dogs

Only for use on dogs and puppies 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.70%
OTHER INGREDIENTS.....	90.30%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease);
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. **READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.**

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette/vial/tube

Drawing of treating animal

1. Remove product tubes/vials from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age or less than 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * 5 to 22 lbs.

- * 23 to 44 lbs.

- * 45 to 88 lbs.

- * 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

Warranty

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
10077 South 134th Street
Omaha, NE
68138 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?

1-888-908-TICK

Made in USA

Sublabel D: Labeling on the Pipette

Body of pipette/vial/tube:

Contains: fipronil 9.70%

LoradoChem

[0.023 fl.oz.]

Or

[0.0045 fl.oz.]

Or

[0.091 fl.oz.]

Or

[0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name] For
Dogs

[For Dogs 5- 22 lbs. 8 weeks or older]

Or

[For Dogs 23-44 lbs. 8 weeks or older]

Or

[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[1.5x1.5 cm Cat prohibition icon]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See package insert for directions for use.

EPA Reg. No. 86230-2

Sublabel E: Stickers for Re-application Reminders [Optional]

LC-2010-2

[or other approved alternate brand name]

**For Dogs
Care Card**

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw

Date of Application

Month 2

Drawing of paw

Date of Application

Month 3

Drawing of paw

Date of Application

[Month 4

Drawing of paw

Date of Application

Month 5

Drawing of paw

Date of Application

Month 6

Drawing of paw

Date of Application

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name:

lbs.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 21, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

IAIN WEATHERSTON, PH.D.
J&T ACCOCIATES LLC
LORADOCHEM, INC.
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85395-

PRODUCT NAME: LC-2010-2 FIPRONIL FOR DOGS
COMPANY NAME: LORADOCHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86230-2
EPA RECEIPT DATE: 05/20/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J.", is written over the word "Sincerely,".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

TRANSMITTAL DOCUMENT

NAME & ADDRESS OF APPLICANT

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
A FAST TRACK LABEL AMENDMENT

TRANSMITTAL DATE

May 19, 2014

LIST OF SUBMITTED MATERIAL

VOLUME 86230-2-1

Administrative Volume: Correspondence, Application,
Current SAL, and Draft Label

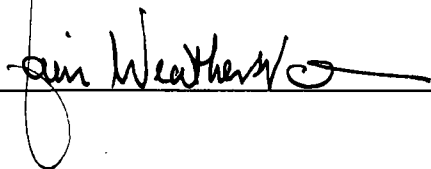
PRIA INFORMATION

Not subject to PRIA fees

COMPANY AGENT/CONTACT

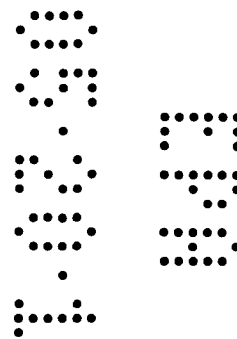
Iain Weatherston, Ph.D.
J&T Associates, LLC
4061 North 156th Drive
Goodyear, AZ 85395
623-535-4055 / iweatherston@cox.net

AGENT SIGNATURE



DATE

19 May 2014.



APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
A SPOT-ON FOR CONTROL OF FLEAS, TICKS, CHEWING LICE, AND MOSQUITOES

A FAST TRACK LABEL AMENDMENT
Non-PRIA

APPLICANT

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

VOLUME 86230-2-1

**ADMINISTRATIVE VOLUME: CORRESPONDENCE, APPLICATION, CURRENT SAL, AND
DRAFT LABEL**

DATA REQUIREMENTS

40 CFR 152.50

AUTHORS

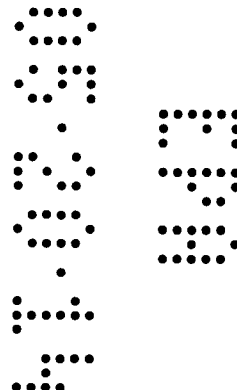
Iain Weatherston, Ph.D.
Megha Shah Even, M.S.

DATE COMPLETED

May 16, 2014

SUBMITTER

J&T Associates LLC
4061 North 156th Drive
Goodyear, AZ 85395



CONFIDENTIALITY CLAIMS

STATEMENT OF NO DATA CONFIDENTIALITY

No data in this volume is claimed confidential on the basis of its falling within the scope of FIFRA § 10(d)(1) (A), (B) or (C).

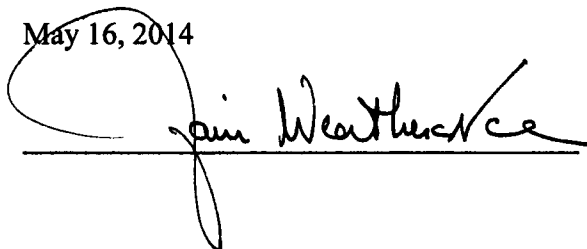
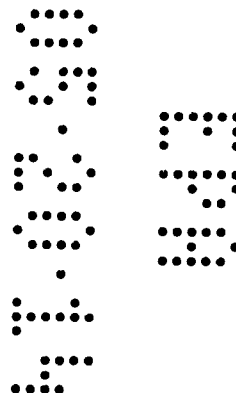
COMPANY: LoredoChem Inc.

COMPANY AGENT: Iain Weatherston, Ph.D.

TITLE: Agent to LoredoChem Inc.

DATE: May 16, 2014

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line. The signature is stylized with a large loop at the beginning and a long, sweeping tail.

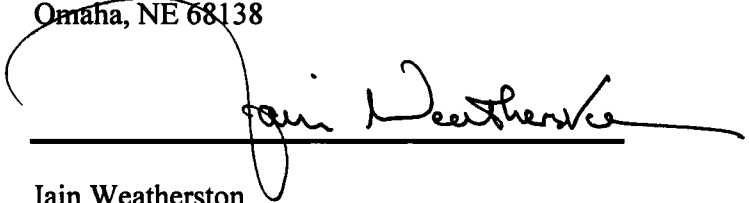
**VOLUNTARY RELEASE OF INFORMATION TO STATES AND FOREIGN
GOVERNMENTS (40 CFR 158.33(c)(4))**

I authorize the Environmental Protection Agency to release any information contained in this document to State and foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.

COMPANY:

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line. A large, loopy flourish extends from the end of the signature.

TYPED NAME OF SIGNER:

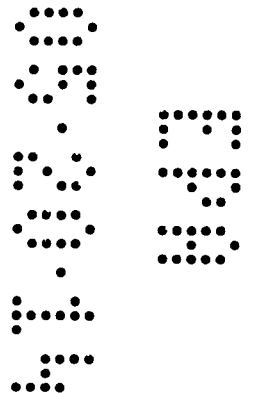
Iain Weatherston

TITLE OF SIGNER:

Agent to LoredoChem Inc.

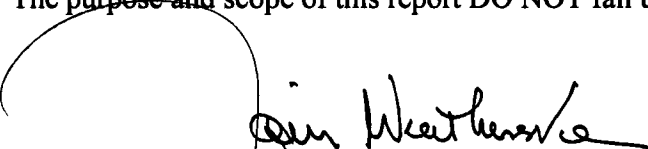
DATE:

May 16, 2014



GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report DO NOT fall under the requirements of 40 CFR 160.



Iain Weatherston
For Applicant and Submitter

May 16, 2014
Date

CONTENTS

COVER PAGE	1.
CONFIDENTIALITY CLAIMS	2.
VOLUNTARY RELEASE OF INFORMATION TO STATES AND FOREIGN GOVERNMENTS	3.
GOOD LABORATORY PRACTICES STATEMENT	4.
CONTENTS	5.
LETTER OF INTRODUCTION	6.
APPLICATION FOR PESTICIDE REGISTRATION [EPA FORM 8570-1]	9.
CURRENT SAL for LC-2010-2 FIPRONIL FOR DOGS	10.
DRAFT LABEL for LC-2010-2 FIPRONIL FOR DOGS (marked-up and clean copies)	25.

J&T Associates LLC

4061 North 156th Drive, Goodyear, AZ 85395

Iain Weatherston, Ph.D.
Director
623-535-4055/623-317-9013
E-mail: iweatherston@cox.net

May 16, 2014

Mr. Richard Gebken, PM 10
US EPA-OPP Insecticide Branch (7504P)
Document Processing Desk (AMEND)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Fast Track Amendment per PR Notice 98-10 in response to
Agency letter dated April 14, 2014

COMPANY: LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

CONTACT: Iain Weatherston, Ph.D, J&T Associates LLC
[contact information as per letterhead]

PRODUCT: LC-2010-2 Fipronil for Dogs
[EPA File Symbol 86230-2]

Dear Mr. Gebken:

As consultant for, and on behalf of LoredoChem Inc., I submit for your review and approval a fast track amendment to add additional marketing claims to the label for LC-2010-2 Fipronil for Dogs (EPA Reg. No. 86230-2). This amendment requires no scientific review of data and is submitted in response to Agency letter dated April 14, 2014 (see attached).

In addition to this letter, this application contains:

- A fully executed application for pesticide registration [8570-1]
- A copy of the current EPA-stamped approved label
- A redline copy of the proposed label changes (1 hard copy and 1 copy on CD-ROM)
- A clean copy of the proposed label changes (1 hard copy and 1 copy on CD-ROM)

This application is not subject to PRIA fees. Should you have any questions or further information is required, please do not hesitate to contact me.

Sincerely,



Iain Weatherston
Consultant to LoredoChem Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. / LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc. 10077 South 134th Street Omaha, NE 68138 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>April 14, 2014</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast track amendment per PR Notice 98-10 (non-PRIA):
Amendment to the LC-2010-2 Fipronil for Dogs label to add additional marketing claims.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name IAIN WEATHERSTON		Title Agent, LoredoChem Inc.		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent, LoredoChem Inc.			
4. Typed Name IAIN WEATHERSTON		5. Date May 16, 2014			

S: 952538

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ NoBillable: ☐ Yes ☒ No

Company: 86230 LORADOCEM, INC.



Risk Manager: Registration Division, Risk Management Team 10



Product #: 86230-2 Product Name: LC-2010-2 FIPRONIL FOR DOGS

Override#:

Me Too

Section3: 65331-3

Me Too Product

Name: FIPAIRA FOR DOGS

Application Date: 16-May-2014



OPP Rec'd Date: 20-May-2014



Front End Date: 20-May-2014



Risk Manager Send Date: 21-May-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

AMENDMENT

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

De

Paper Label

Electronic Label

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Iain Weatherston
LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

APR 14 2014

Subject: Addition of ABN and Marketing Claims
Product Name: LC-2010-2 Fipronil for Dogs
EPA Reg. Number: 86230-2
Submission date: February 10, 2014
Decision Number: 487966

Dear Mr. Weatherston

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **not acceptable**.

- 1) It was just discovered that you have the same Alternate Brand Names for EPA Reg. No. 86230-1 and 86230-2. Each registered brand name needs to be specific to its product. You must revise or remove duplicate Alternate Brand Names for these two products.
- 2) The following Marketing Claims must be removed from the proposed label, or revised.
 - a. **[NEW]**
 - b. **[[New] Direct to skin [applicator]][tube][vial][pipette]**
 - c. **XS/S/M/L/XL**
 - d. **[[NEW!] Clean cut [open][applicator!]**
 - e. **[[NEW!] No mess [open][applicator]]**
 - f. **[[NEW]Clip-tip design [applicator][!]**
 - g. **[Contains [the][same]active ingredient used in [FRONTLINE TopSpot for Dogs (or any ABN)][FRONTLINE brand products.]*]**
 - h. **Compare to [FRONTLINE TopSpot for Dogs (or any ABN)][FRONTLINE brand products], contains [the][an][same] active ingredient.*]**
 - i. **Compare to [FRONTLINE TopSpot for Dogs (or any ABN) [FRONTLINE brand products], contains [the][an][same] active ingredient fipronil.*]**
 - j. **[[Brand Name] [products][This product] contain(s) fipronil, compared to [the][an] [same] active ingredient used in] FRONTLINE TopSpot for Dogs (or any ABN)] [FRONTLINE brand products]*]**

- k. [[Brand Name][This product] is not manufactured or distributed by [Merial]
[Company name], the makers of [FRONTLINE TopSpot for Dogs (or any ABN)]
[FRONTLINE brand products]*]
- l. [[Brand Name] [This product][FRONTLINE] [FRONTLINE TopSpot is a
registered trademark of [Merial][Company name].]
- m. [[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]
[*FRONTLINE][Frontline] brand products may contain additional active
ingredients.]

If you have any questions, you may contact Richard Gebken at 703-305-6701.

Sincerely,



Richard Gebken
Team Leader / Product Manager 10
Insecticide Branch
Registration Division (7505P)

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

[] -- alternate verbiage

“Pipette/Vial/Tube/Applicator” can be used interchangeably

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.70%
OTHER INGREDIENTS.....90.30%
TOTAL.....100.00%

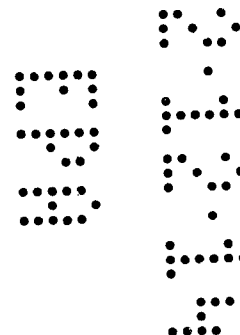
KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2

*Denied
4/14/14*



Sublabel A: Box Label

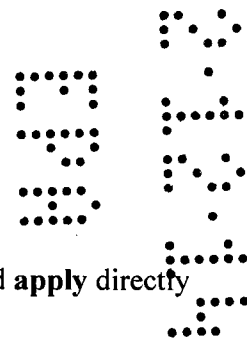
[Front Panel of Box]

LC-2010-2
[Alternate Brand Names]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]
[Sergeant's® PetArmor [II]]
[PetArmor [II]]

FOR DOGS

3 (Drawing of pipette/vial/tube)
[Alternate Packaging]
[6 (Drawing of pipette/vial/tube)]
[1 (Drawing of pipette/vial/tube)]
[2 (Drawing pipette/vial/tube)]
[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]
[24 (Drawing of pipette/vial/tube)]
[Pipette[s]/Vial[s]/Tube[s]]

- Kills fleas, ticks, chewing lice & Mosquitoes
- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control
- [New]
- [[New] Direct to skin [applicator][tube][vial][pipette]]
- Bonus
- Buy "x" get "y" free
- Get "x%" free
- "X%" More Free
- Clip, Part, Squeeze
- XS/S/M/L/XL
- [Easy to use][applicator]
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin



- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **squeeze** directly onto the skin
- ✓ • [[NEW!] Clean cut [open][applicator!]
- ✓ • [[NEW!] No mess [open][applicator]]
- ✓ • [[NEW] Clip-tip design [applicator][!]]
- ✓ • [Contains [the][same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)][FRONTLINE® brand products.]*]
- ✓ • Compare to [FRONTLINE® Top Spot ® for Dogs (or any ABN)][FRONTLINE® brand products], contains [the] [an] [same] active ingredient.*]
- ✓ • Compare to [FRONTLINE® Top Spot ® for Dogs (or any ABN)][FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil*]
- ✓ • [[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient used in]FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- ✓ • [[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- ✓ • [[Brand name] [This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- ✓ • [[Brand name] [This product][FRONLTLINE®] [Frontline® Top Spot ® is a registered trademark of [Merial®] [Company name].]
- ✓ • [[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.70%

OTHER INGREDIENTS.....90.30%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Contains 3-0.023 fl.oz (0.67 mL) pipettes]

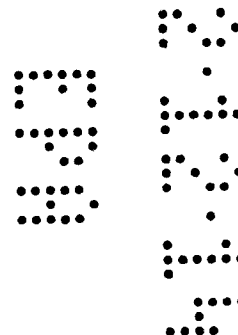
Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

(Picture of dog)

(1.5x1.5 cm Cat prohibition Icon)

Or
[Contains 3-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 3-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 6-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 6-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 6-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 6-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 1-0.023 fl.oz (0.67 mL) pipette]
Or
[Contains 1-0.045 fl.oz. (1.34 mL) pipette]
Or
[Contains 1-0.091 fl.oz. (2.68 mL) pipette]
Or
[Contains 1-0.136 fl.oz (4.02 mL) pipette]
Or
[Contains 2-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 2-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 2-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 2-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 4-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 4-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 4-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 4-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 5-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 5-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 5-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 5-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 12-0.023 fl.oz (0.67 mL) pipettes]



Or
 [Contains 12-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 12-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 12-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 24-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 24-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 24-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 24-0.136 fl.oz (4.02 mL) pipettes]

[Label identifiers that will be used to identify each respective package size contained within the box.]

✓ Compare to Frontline® Top Spot same active ingredient*

[*[FRONTLINE®][Frontline®] brand products may contain additional active ingredients.]

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older]

Or ...[ONLY on dogs weighing 23-44 lbs. and 8 weeks or older].

Or ...[ONLY on dogs weighing 45-88 lbs.]

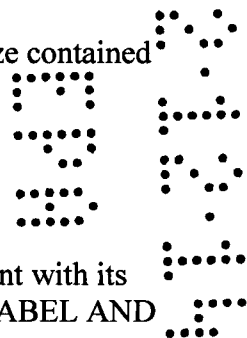
Or ...[ONLY on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one tube/vial/pipette per dog per month.

[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND



ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Remove product tube/vial from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in XXXXX

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

3 (Drawing of pipette)

[6 (Drawing of pipette)]

[1 (Drawing of pipette)]

pipette[s]

[2 (Drawing of pipette/vial/tube)]

[4 (Drawing of pipette/vial/tube)]

[5 (Drawing of pipette/vial/tube)]

[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

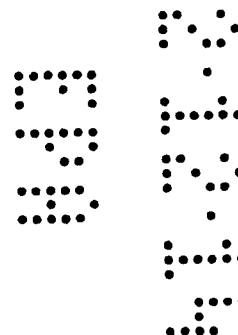
LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older] 3 (Drawing of pipette)
Or [6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older] [1 (Drawing of pipette)]
Or pipette[s]
[Only use on dogs 45-88 lbs.] [2,4,5,12, or 24]
Or
[Only use on dogs 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained within the box.]

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
[2,4,5,12,or 24]
Pipette[s]



Sublabel B: Package Insert

LC-2010-2 [or other approved alternate brand name] For Dogs

Only for use on dogs and puppies 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89 lbs.]

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.70%
OTHER INGREDIENTS.....	90.30%
TOTAL.....	100.00%

Compare to Frontline® Top Spot same active ingredient*

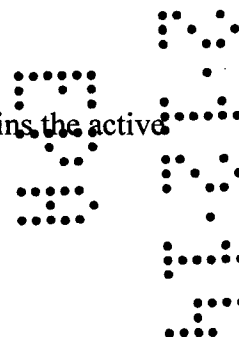
KEEP OUT OF REACH OF CHILDREN CAUTION

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.



Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette/vial/tube

Drawing of treating animal

- Why Brackets?*
1. Remove product tubes/vials from the package
 2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
 3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoredoChem or name of distributor] at 1-888-908-TICK.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

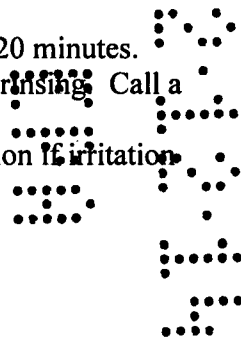
First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.



PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age or < 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * 5 to 22 lbs.
- * 23 to 44 lbs.
- * 45 to 88 lbs.
- * 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

Warranty

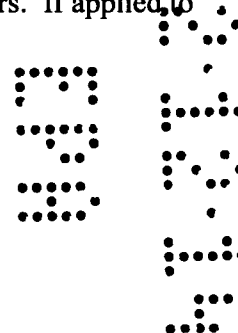
To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA



EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK
Made in XXXXX

Sublabel D: Labeling on the Pipette

Body of pipette/vial/tube:

Contains: fipronil (9.70%)

LoradoChem

[0.023 fl.oz.]

Or

[0.0045 fl.oz.]

Or

[0.091 fl.oz.]

Or

[0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name] For
Dogs

[For Dogs 5- 22 lbs. 8 weeks or older]

Or

[For Dogs 23-44 lbs. 8 weeks or older]

Or

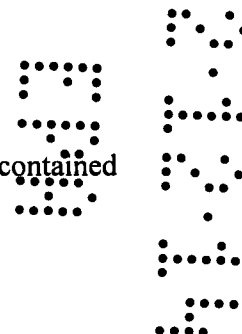
[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[1.5x1.5 cm Cat prohibition icon]





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 19, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

IAIN WEATHERSTON, PH.D.
J&T ACCOCIATES LLC
LORADOCHEM, INC.
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85395-

PRODUCT NAME: LC-2010-2 FIPRONIL FOR DOGS
COMPANY NAME: LORADOCHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86230-2
EPA RECEIPT DATE: 02/12/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

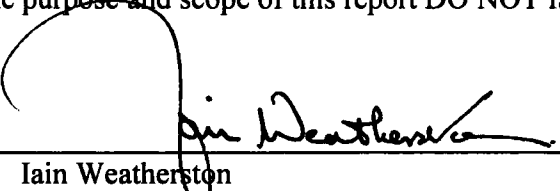
Sincerely,

A handwritten signature in black ink, appearing to be "S. J. ...".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

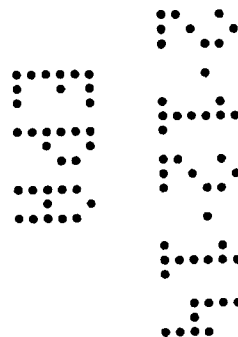
GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report DO NOT fall under the requirements of 40 CFR 160.



Iain Weatherston
For Applicant and Submitter

February 10, 2014
Date



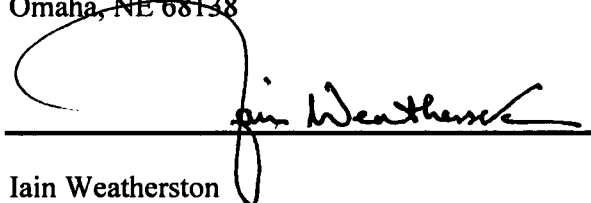
**VOLUNTARY RELEASE OF INFORMATION TO STATES AND FOREIGN
GOVERNMENTS (40 CFR 158.33(c)(4))**

I authorize the Environmental Protection Agency to release any information contained in this document to State and foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.

COMPANY:

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line.

TYPED NAME OF SIGNER:

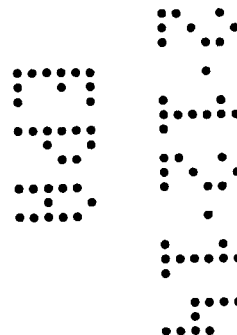
Iain Weatherston

TITLE OF SIGNER:

Agent to LoredoChem Inc.

DATE:

February 10, 2014



CONFIDENTIALITY CLAIMS

STATEMENT OF NO DATA CONFIDENTIALITY

No data in this volume is claimed confidential on the basis of its falling within the scope of FIFRA § 10(d)(1) (A), (B) or (C).

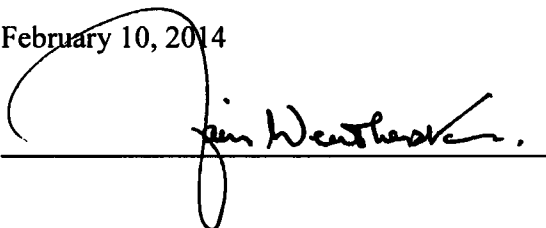
COMPANY: LoredoChem Inc.

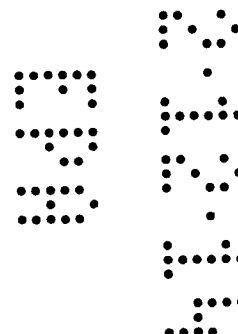
COMPANY AGENT: Iain Weatherston, Ph.D.

TITLE: Agent to LoredoChem Inc.

DATE: February 10, 2014

SIGNATURE:





APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS

A SPOT-ON FOR CONTROL OF FLEAS, TICKS, CHEWING LICE, AND MOSQUITOES

A FAST TRACK LABEL AMENDMENT

Non-PRIA

APPLICANT

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

VOLUME 86230-2-1

**ADMINISTRATIVE VOLUME: CORRESPONDENCE, APPLICATION, CURRENT SAL, AND
DRAFT LABEL**

DATA REQUIREMENTS

40 CFR 152.50

AUTHORS

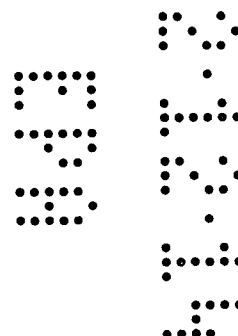
Iain Weatherston, Ph.D.
Megha Shah Even, M.S.

DATE COMPLETED

February 10, 2014

SUBMITTER

J&T Associates LLC
4061 North 156th Drive
Goodyear, AZ 85395



TRANSMITTAL DOCUMENT

NAME & ADDRESS OF APPLICANT

LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
A FAST TRACK LABEL AMENDMENT

TRANSMITTAL DATE

February 11, 2014

LIST OF SUBMITTED MATERIAL

VOLUME 86230-2-1

Administrative Volume: Correspondence, Application,
Current SAL, and Draft Label

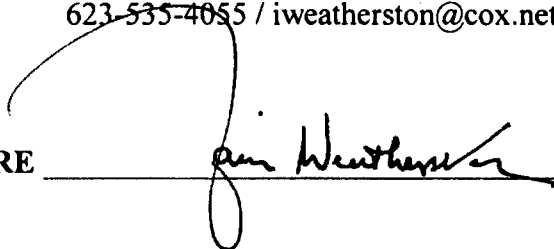
PRIA INFORMATION

Not subject to PRIA fees

COMPANY AGENT/CONTACT

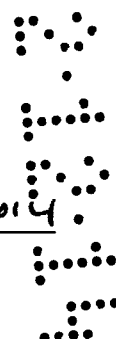
Iain Weatherston, Ph.D.
J&T Associates, LLC
4061 North 156th Drive
Goodyear, AZ 85395
~~623-535-4055~~ / iweatherston@cox.net

AGENT SIGNATURE



DATE

2/11/2014



J&T Associates LLC

4061 North 156th Drive, Goodyear, AZ 85395

Iain Weatherston, Ph.D.
Director
623-535-4055/623-317-9013
E-mail: iweatherston@cox.net

February 10, 2014

Mr. Richard Gebken, PM 10
US EPA-OPP Insecticide Branch (7504P)
Document Processing Desk (AMEND)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Fast Track Amendment per PR Notice 98-10 in response to
Agency letter dated Jan 29, 2014

COMPANY: LoredoChem Inc.
10077 South 134th Street
Omaha, NE 68138

CONTACT: Iain Weatherston, Ph.D, J&T Associates LLC
[contact information as per letterhead]

PRODUCT: LC-2010-2 Fipronil for Dogs
[EPA File Symbol 86230-2]

Dear Mr. Gebken:

As consultant for, and on behalf of LoredoChem Inc., I submit for your review and approval a fast track amendment to add additional marketing claims to the label for LC-2010-2 Fipronil for Dogs (EPA Reg. No. 86230-2). This amendment requires no scientific review of data and is submitted in response to Agency letter dated January 29, 2014 (see attached).

In addition to this letter, this application contains:

- A fully executed application for pesticide registration [8570-1]
- A copy of the current EPA-stamped approved label
- A redline copy of the proposed label changes (1 hard copy and 1 copy on CD-ROM)
- A clean copy of the proposed label changes (1 hard copy and 1 copy on CD-ROM)

This application is not subject to PRIA fees. Should you have any questions or further information required, please do not hesitate to contact me.

Sincerely,


Iain Weatherston
Consultant to LoredoChem Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. / LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc. 10077 South 134th Street Omaha, NE 68138 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated Jan 29, 2014	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast track amendment per PR Notice 98-10 (non-PRIA):
Amendment to the LC-2010-2 Fipronil for Dogs label to add additional marketing claims.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name IAIN WEATHERSTON		Title Agent, LoredoChem Inc.		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent, LoredoChem Inc.			
4. Typed Name IAIN WEATHERSTON		5. Date February 10, 2014			

S: 947704

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 86230 LORADOCEM, INC.



Risk Manager: Registration Division, Risk Management Team 10

Print Letter

Enter More Information

Tracking

Product #: 86230-2 Product Name: LC-2010-2 FIPRONIL FOR DOGS

Override#:

Me Too

Section3: 85331-3

Me Too

Product Name: FIPAIRA FOR DOGS

Application Date: 10-Feb-2014



OPP Rec'vd Date: 12-Feb-2014



Front End Date: 12-Feb-2014



Risk Manager Send Date: 19-Feb-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Paper Label	
Electronic Label	
<input type="button" value="Previous"/> <input type="button" value="Next"/>	

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ian Weatherston
Loradochem Inc.
c/o J&T Associates LLC
4061 N 156th Drive
Goodyear, AZ 85395

JAN 29 2014

Subject: Notification to Change Labeling Verbiage

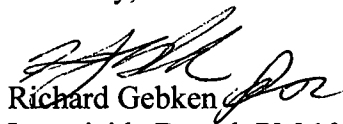
Dear Mr. Weatherston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated October 28, 2013 for the product EPA Reg. No. 86230-2. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested **does not clearly fall within the scope of PRN 98-10 and will require additional administrative review of the related files.**

Please be advised that PRNs are provided as guidance; they are not considered regulation by the Agency. Therefore, the RD reserves the right to make the above determination and concludes that this action must be submitted by you as an amendment. No further processing of this action will occur until a resubmission is made. The RD has determined that this action is denied and our records have been updated accordingly.

If you have any questions, please call me directly at 703-305-6701.

Sincerely,


Richard Gebken
Insecticide Branch PM 10 Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number LoradoChem Inc. / 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Loradochem Ltd/ LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Loradochem Inc. c/o J&T Associates LLC, 4061 N 156th Drive, Goodyear, AZ 85395 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label verbiage changes. as per PRN 98-10. "This notification is consistent with the provisions of PRN 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec.1001 to wilfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name IAIN WEATHERSTON		Title Authorized agent to Loradochem Inc.		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Authorized agent to Loradochem Inc.			
4. Typed Name IAIN WEATHERSTON		5. Date October 28, 2013			

J&T Associates LLC

Iain Weatherston Ph.D.
Director
623-217-9013 / 623-535-4055
E-mail: iweatherston@cox.net

October 28, 2013

Notifications Coordinator
U.S. EPA – OPP – RD
Document Processing Desk (NOTIF)
One Potomac Yard
2777, South Crystal Drive,
Arlington 22202

SUBJECT: Notification to change labeling verbiage on four pet spot-on products.

COMPANIES: Loradochem Inc. and FidoPharm Inc.
c/o 4061 North 156th Drive, Goodyear, AZ 85395.

CONTACT: Iain Weatherston, Ph.D., J&T Associates LLC.
[contact information as per letterhead]

PRODUCTS: ~~LC-2010-1 Fipronil For Cats [86230-1]~~
LC-2010-2 Fipronil For Dogs [86230-2]
~~LC-2010-3 Fipronil and S-Methoprene For Cats [85495-1]~~
~~LC-2010-4 Fipronil and S-Methoprene For Dogs [85495-2]~~

Dear Coordinator:

As agent for and on behalf of LoradoChem Inc., and FidoPharm Inc., I am submitting these labels to change certain verbiage which falls under the provisions of PRN 98-10.

Attached to this letter, for each product, there is a fully executed application for pesticide registration form (8570-1), a copy of the current stamped approved labels and two copies of the new draft labels one marked with the changes up (in red), and a clean copy.

If there are any questions or you require further information, please do not hesitate to contact me at iweatherston@cox.net or by telephone at 623-535-4055.

Sincerely,


Iain Weatherston

Attachments:

Application for pesticide application (8570-1) for LC-2010-1 with certification
Application for pesticide application (8570-1) for LC-2010-2 with certification
Application for pesticide application (8570-1) for LC-2010-3 with certification
Application for pesticide application (8570-1) for LC-2010-4 with certification
Current LC-2010-1 label accepted on June 26, 2013
Current LC-2010-2 label accepted on June 26, 2013
Current LC-2010-3 label accepted on June 26, 2013
Current LC-2010-4 label accepted on June 26, 2013
Two copies of updated draft label for LC-2010-1
Two copies of updated draft label for LC-2010-2
Two copies of updated draft label for LC-2010-3
Two copies of updated draft label for LC-2010-4

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

[] -- alternate verbiage

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.70%

OTHER INGREDIENTS.....90.30%

TOTAL.....100.00%

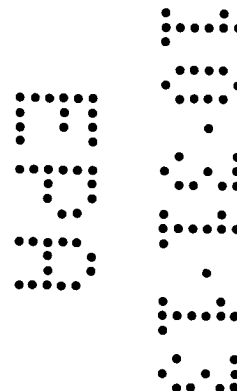
KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2

Rejected



Sublabel A: Box Label

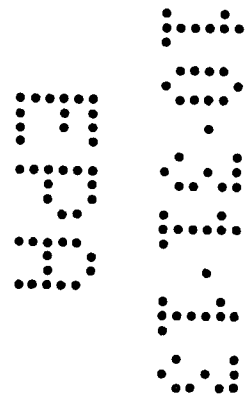
[Front Panel of Box]

LC-2010-2
[Alternate Brand Names]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]
[Sergeant's® Pet Armor [II]]
[Pet Armor [II]]

FOR DOGS

3 (Drawing of pipette/vial/tube)
[Alternate Packaging]
[6 (Drawing of pipette/vial/tube)]
[1 (Drawing of pipette/vial/tube)]
[2 (Drawing of pipette/vial/tube)]
[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]
[24 (Drawing of pipette/vial/tube)]
[Pipette[s]/Vial[s]/Tube[s]

- Kills fleas, ticks, chewing lice & Mosquitoes
- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control
- [New]
- [[New] Direct to skin [applicator][tube][vial][pipette]
- Bonus
- Buy “x” get “y” free
- Get “x%” free
- “X%” More Free
- Clip, Part, Squeeze
- XS/S/M/L/XL
- [Easy to use][applicator]
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin



- Easier than ever applicator lets you clip the tip, part the fur [hair] and squeeze directly onto the skin
- [[NEW!] Clean cut [open][applicator!]
- [[NEW!] No mess [open][applicator]]
- [[NEW] Clip-tip design [applicator][!]]
- [Contains [the][same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)][FRONTLINE® brand products.]*]
- Compare to [FRONTLINE® Top Spot ® for Dogs (or any ABN)][FRONTLINE® brand products], contains [the] [an] [same] active ingredient.*]
- Compare to [FRONTLINE® Top Spot ® for Dogs (or any ABN)][FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil*]
- [[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient used in]FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- [[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- [[Brand name] [This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot ® for Dogs (or any ABN)] [FRONTLINE® brand products]*]
- [[Brand name] [This product][FRONTLINE®] [Frontline® Top Spot ® is a registered trademark of [Merial®] [Company name].]
- [[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.70%

OTHER INGREDIENTS.....90.30%

TOTAL.....100.00%

(Picture of dog)

KEEP OUT OF REACH OF CHILDREN

CAUTION

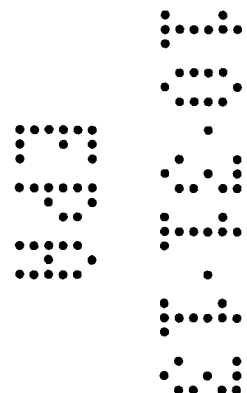
[Contains 3-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

(1.5x1.5 cm Cat prohibition Icon)

Or
 [Contains 3-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 3-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 6-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 6-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 6-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 6-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 1-0.023 fl.oz (0.67 mL) pipette]
 Or
 [Contains 1-0.045 fl.oz. (1.34 mL) pipette]
 Or
 [Contains 1-0.091 fl.oz. (2.68 mL) pipette]
 Or
 [Contains 1-0.136 fl.oz (4.02 mL) pipette]
 Or
 [Contains 2-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 2-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 2-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 2-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 4-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 4-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 4-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 4-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 5-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 5-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 5-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 5-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 12-0.023 fl.oz (0.67 mL) pipettes]



Or
 [Contains 12-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 12-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 12-0.136 fl.oz (4.02 mL) pipettes]
 Or
 [Contains 24-0.023 fl.oz (0.67 mL) pipettes]
 Or
 [Contains 24-0.045 fl.oz. (1.34 mL) pipettes]
 Or
 [Contains 24-0.091 fl.oz. (2.68 mL) pipettes]
 Or
 [Contains 24-0.136 fl.oz (4.02 mL) pipettes]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Compare to Frontline® Top Spot same active ingredient*

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older]

Or ...[ONLY on dogs weighing 23-44 lbs. and 8 weeks or older].

Or ...[ONLY on dogs weighing 45-88 lbs.]

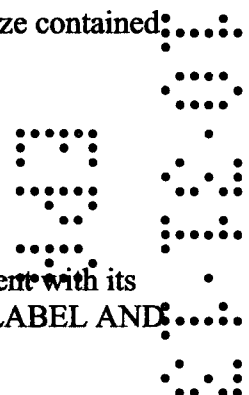
Or ...[ONLY on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one tube/vial/pipette per dog per month.

[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND



ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Remove product tube/vial from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in XXXXX

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

3 (Drawing of pipette)

[6 (Drawing of pipette)]

[1 (Drawing of pipette)]

pipette[s]

[2 (Drawing of pipette/vial/tube)]

[4 (Drawing of pipette/vial/tube)]

[5 (Drawing of pipette/vial/tube)]

[12 (Drawing of pipette/vial/tube)]

[24 (Drawing of pipette/vial/tube)]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

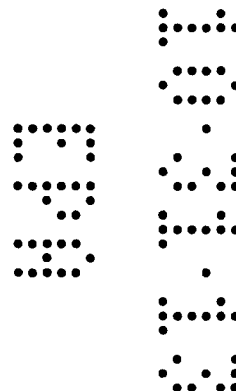
LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older] 3 (Drawing of pipette)
Or [6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older] [1 (Drawing of pipette)]
Or pipette[s]
[Only use on dogs 45-88 lbs.] [2,4,5,12, or 24]
Or
[Only use on dogs 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained within the box.]

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
[2,4,5,12,or 24]
Pipette[s]



Sublabel B: Package Insert

LC-2010-2 [or other approved alternate brand name] For Dogs

Only for use on dogs and puppies 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89 lbs.]

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.70%
OTHER INGREDIENTS.....	90.30%
TOTAL.....	100.00%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN

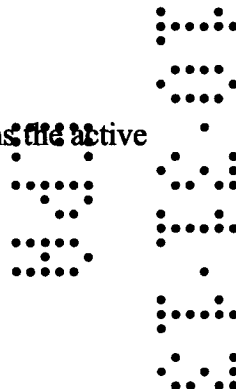
CAUTION

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.



Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. **READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.**

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs. [23 lbs.] [45 lbs.] [89lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette/vial/tube

Drawing of treating animal

1. Remove product tubes/vials from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age or < 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * 5 to 22 lbs.

- * 23 to 44 lbs.

- * 45 to 88 lbs.

- * 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

Warranty

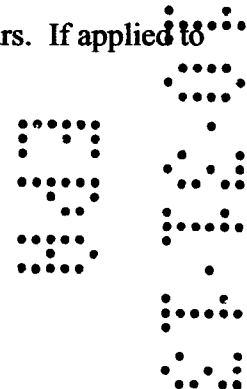
To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA



EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?

1-888-908-TICK

Made in XXXXX

Sublabel D: Labeling on the Pipette

Body of pipette/vial/tube:

Contains: fipronil (9.70%)

LoradoChem

[0.023 fl.oz.]

Or

[0.0045 fl.oz.]

Or

[0.091 fl.oz.]

Or

[0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name] For
Dogs

[For Dogs 5- 22 lbs. 8 weeks or older]

Or

[For Dogs 23-44 lbs. 8 weeks or older]

Or

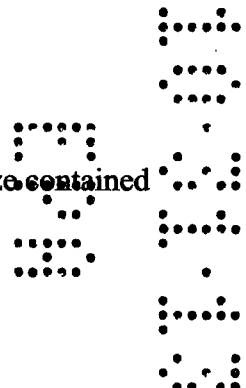
[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[1.5x1.5 cm Cat prohibition icon]



KEEP OUT OF REACH OF CHILDREN
CAUTION
See package insert for directions for use.

EPA Reg. No. 86230-2

Sublabel E: Stickers for Re-application Reminders [Optional]

LC-2010-2
[or other approved alternate brand name]
For Dogs
Care Card

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw

Date of Application

Month 2

Drawing of paw

Date of Application

Month 3

Drawing of paw

Date of Application

[Month 4

Drawing of paw

Date of Application

Month 5

Drawing of paw

Date of Application

Month 6

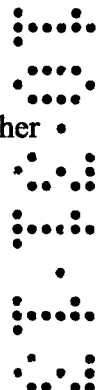
Drawing of paw

Date of Application

] Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name:

lbs.





S: 942957

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 86230 LORADOCEM, INC.



Risk Manager: Registration Division, Risk Management Team 10

Product #: 86230-2 Product Name: LC-2010-2 FIPRONIL FOR DOGS

Override#:

Me Too

Section3: 85331-3

Me Too

Product Name: FIPAIRA FOR DOGS

Application Date: 28-Oct-2013



OPP Rec'd Date: 31-Oct-2013



Front End Date: 31-Oct-2013



Risk Manager Send Date: 31-Oct-2013



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label Notification to change certain verbiage (as indicated)

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Paper Label

View/Edit

Unacceptable,
Must be so



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 23, 2013

Iain Weatherston, Agent
LoradoChem Inc.
10077 South 134th Street
Omaha, NE 68138

Subject: Notification of alternate sources of active ingredients for two LoradoChem fipronil products and two FidoPharm fipronil plus S-methoprene spot-on products

Dear Mr. Weatherston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 28, 2013 for the product 86230-2. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested **does not clearly fall within the scope of PRN 98-10 and will require additional administrative review of the related files**. A summary of our findings include:

- For each and every Component in Formulation, supplier name and address are required. "Commodity item obtained from various sources" is not an acceptable site of source.

Please be advised that PRNs are provided as guidance; they are not considered regulation by the Agency. Therefore, the RD reserves the right to make the above determination and concludes that this action must be submitted by you as an amendment. No further processing of this action will occur until a resubmission is made. The RD has determined that this action is denied and our records have been updated accordingly.

If you have any questions, please call me directly at 703-305-6701 or Carlyn Petrella of my staff at 703-347-0439.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Insecticide Branch PM 10 Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. / LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc. 10077 South 134th Street Omaha, NE 68138 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification of alternate source(s) for TGA(s) per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name IAIN WEATHERSTON		Title Agent, LoredChem Inc.		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent, LoredChem Inc.			
4. Typed Name IAIN WEATHERSTON		5. Date November 28, 2013			

J&T Associates LLC

Iain Weatherston Ph.D.
Director
623-217-9013 / 623-535-4055
E-mail: iweatherston@cox.net

November 30, 2013

Notifications Coordinator
U.S. Environmental Protection Agency
OCSPP – OPP – RD (NOTIF)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

✓ Richard Gebken
U.S. Environmental Protection Agency
OCSPP – OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

SUBJECT: Notification of alternate sources of active ingredient(s) for two LoradoChem fipronil products and two FidoPharm fipronil plus S-methoprene spot-on products.

COMPANIES: FidoPharm Inc.[85495] and LoradoChem Inc.[86230]
10077 South 134th Street, Omaha, NE 68138.

CONTACT: Iain Weatherston, Ph.D., J&T Associates LLC
[contact information as per letterhead]

PRODUCTS: LC-2010-1 Fipronil for Cats (86230-1); LC-2010-2 Fipronil for Dogs (86230-2); LC-2010-3 Fipronil and S-Methoprene for Cats (85495-1) and LC-2010-4 Fipronil and S-Methoprene for Dogs (85495-2).

Dear Coordinator and Richard:

Referencing my letter to Mr. Gebken of April 8, 2013, our meeting on May 16 and the subsequent minutes discussing and explaining the sale of Velcera (LoradoChem and FidoPharm) to Perrigo and what needed to be done to fully integrate LoradoChem and FidoPharm with Sergeant's Pet Care Products and their product portfolio.

Continuing the integration process, this submission is the notification of alternate sources of the active ingredients (fipronil and fipronil and S-methoprene) to be included in the registration documentation of the four title products. This notification is in compliance with PR Notice 98-10 and 40 CFR 152.46 and so certified on the 8570-1 form (attached) for each of the products.

If there are any questions or further information is required please do not hesitate to contact me at iweatherston@cox.net or by telephone at 623-535-4055.

Sincerely


Iain Weatherston

Attachments:

For LC-2010-1: Fully executed pesticide application form (8570-1) and formulator's exemption statement (8570-27); current CSF (January 16, 2012) and two draft CSF's incorporating the change of sources for the fipronil which can be used to formulate this product.

For LC-2010-2: Fully executed pesticide application form (8570-1) and formulator's exemption statement (8570-27); current CSF (January 16, 2012) and two draft CSF's incorporating the change of sources for the fipronil which can be used to formulate this product.

For LC-2010-3: Fully executed pesticide application form (8570-1) and formulator's exemption statement (8570-27); current CSF (October 31, 2011) and five draft CSF's incorporating the change of sources for the fipronil and S-methoprene which can be used to formulate this product.

For LC-2010-4: Fully executed pesticide application form (8570-1) and formulator's exemption statement (8570-27); current CSF (October 31, 2011) and five draft CSF's incorporating the change of sources for the fipronil and S-methoprene which can be used to formulate this product.

9535



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address LoredoChem Inc. 10077 South 134th Street Omaha, NE 68138	EPA File Symbol/Registration Number 86230-2
	Product Name LC-2010-2 Fipronil for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 1/16/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil (9.7%)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil [REDACTED]	[REDACTED]	[REDACTED]
Fipronil [REDACTED]	[REDACTED]	[REDACTED]
Signature 	Name and Title Iain Weatherston, Agent	Date Nov 28, 2013

Receipt for Section 3

S: 944416

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 86230 LORADOCEM, INC.



Risk Manager: Registration Division, Risk Management Team 10

Product #: 86230-2 Product Name: LC-2010-2 FIPRONIL FOR DOGS

Override#:

Me Too Section3: 85331-3

Me Too Product Name: FIPAIRA FOR DOGS

Application Date: 30-Nov-2013

OPP Rec'd Date: 03-Dec-2013

Front End Date: 03-Dec-2013

Risk Manager Send Date: 03-Dec-2013

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

CSF Notification to add three (3) alternate a.i. sources as two (2) alternate formulations (Alt 1, Alt 2)

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

View/Edit

332
Shenel

Material Sent for Data Extraction

Reg. # 86230-2

Description: AMENDMENT

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 6/26/2013

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 48029

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: KAITLIN KEULER

Phone: 308-8172 Division: RD

Date: 7/9/2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Iain Weatherston, Ph.D.
Agent for LoradoChem, Inc.
J&T Associates LLC
4061 North 156th Drive
Goodyear, AZ 85395

JUN 26 2013

Subject: LC-2010-2 Fipronil for Dogs
EPA Reg. No. 86230-2
Amendment dated 5/27/2013 to incorporate pet spot-on mitigation label language
and transfer the product manufacturing site
EPA Decision No. 480201

Dear Dr. Weatherston,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the transfer of the manufacturer of LC-2010-2 Fipronil for Dogs to Sergeant's Pet Care Products, Inc. facility in Omaha, Nebraska and corresponding label changes are accepted. Additionally, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action. The time-limited registration for this product is extended to one-year from the date of this letter. If a registration extension request is not received prior to that date, the registration of this product will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with this product, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

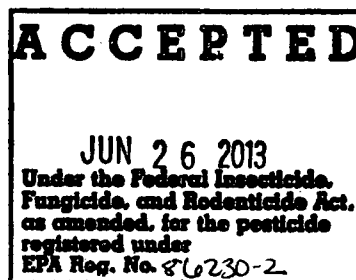
Fipronil.....9.7%
OTHER INGREDIENTS.....90.3%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2



Sublabel A: Box Label

[Front Panel of Box]

LC-2010-2
[Alternate Brand Names]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]

FOR DOGS

3 (Drawing of pipette/vial/tube)
[Alternate Packaging]
[6 (Drawing of pipette/vial/tube)]
[1 (Drawing of pipette/vial/tube)]
[2 (Drawing pipette/vial/tube)]
[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]
[24 (Drawing of pipette/vial/tube)]

[Pipette[s]/Vial[s]/Tube[s] Kills fleas, ticks, chewing lice & Mosquitoes

- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control

[Only use on dogs and puppies 5-22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of dog)

OTHER INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

(1.5x1.5 cm Cat prohibition Icon)

CAUTION

[Contains 3-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 3-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 3-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 6-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 6-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 6-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 6-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 1-0.023 fl.oz (0.67 mL) pipette]

Or

[Contains 1-0.045 fl.oz. (1.34 mL) pipette]

Or

[Contains 1-0.091 fl.oz. (2.68 mL) pipette]

Or

[Contains 1-0.136 fl.oz (4.02 mL) pipette]

Or

[Contains 2-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 2-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 2-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 2-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 4-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 4-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 4-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 4-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 5-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 5-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 5-0.091 fl.oz. (2.68 mL) pipettes]

Or
[Contains 5-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 12-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 12-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 12-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 12-0.136 fl.oz (4.02 mL) pipettes]
Or
[Contains 24-0.023 fl.oz (0.67 mL) pipettes]
Or
[Contains 24-0.045 fl.oz. (1.34 mL) pipettes]
Or
[Contains 24-0.091 fl.oz. (2.68 mL) pipettes]
Or
[Contains 24-0.136 fl.oz (4.02 mL) pipettes]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Compare to Frontline® Top Spot same active ingredient*

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY] on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older

Or ...[ONLY] on dogs weighing 23-44 lbs. and 8 weeks or older.

Or ...[ONLY] on dogs weighing 45-88 lbs.]

Or ...[ONLY] on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one tube/vial/pipette per dog per month.

[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs., including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Remove product tube/vial from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

©2013 LoradoChem, Inc. All rights reserved.

(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in XXXXX

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	[2 (Drawing of pipette/vial/tube)]

Or
[Only use on dogs 89-132 lbs.]

[4 (Drawing of pipette/vial/tube)]
[5 (Drawing of pipette/vial/tube)]
[12 (Drawing of pipette/vial/tube)]
[24 (Drawing of pipette/vial/tube)]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older] 3 (Drawing of pipette)
Or [6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older] [1 (Drawing of pipette)]
Or pipette[s]
[Only use on dogs 45-88 lbs.] [2,4,5,12, or 24]
Or
[Only use on dogs 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained within the box.]

[Left side panel of Box]

Lot Number:

3 (Drawing of pipette)
[6 (Drawing of pipette)]
[1 (Drawing of pipette)]
[2,4,5,12,or 24]
Pipette[s]

Sublabel B: Package Insert

LC-2010-2 [or other approved alternate brand name] For Dogs

Only for use on dogs and puppies 8 weeks or older and ≥ 5 lbs.

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.7%
OTHER INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN CAUTION

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND

ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs., including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette/vial/tube

Drawing of treating animal

1. Remove product tubes/vials from the package
2. {separate one tube/vial from the others. Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Side Effects:

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [LoradoChem or name of distributor] at 1-888-908-TICK.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age or < 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * 5 to 22 lbs.
- * 23 to 44 lbs.
- * 45 to 88 lbs.
- * 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one pipette/vial/tube per dog per month

Warranty

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition icon]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK
Made in XXXXX

Sublabel D: Labeling on the Pipette

Body of pipetyte/vial/tube:

Contains: fipronil (9.7%)

LoradoChem

[0.023 fl.oz.]

Or

[0.0045 fl.oz.]

Or

[0.091 fl.oz.]

Or

[0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name] For
Dogs

[For Dogs 5- 22 lbs. 8 weeks or older]

Or

[For Dogs 23-44 lbs. 8 weeks or older]

Or

[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[1.5x1.5 cm Cat prohibition icon]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See package insert for directions for use.

EPA Reg. No. 86230-2

Sublabel E: Stickers for Re-application Reminders [Optional]

LC-2010-2

[or other approved alternate brand name]

**For Dogs
Care Card**

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw

Date of Application

Month 2

Drawing of paw

Date of Application

Month 3

Drawing of paw

Date of Application

[Month 4

Month 5

Month 6

Drawing of paw
<hr/>
Date of Application

Drawing of paw
<hr/>
Date of Application

Drawing of paw
<hr/>
Date of Application

]

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name:

lbs.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., 1020 Stony Hill Road, Suite 200, Yardley, PA 19067 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See letter of introduction for a full explanation of the amendment to the registration and label.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Iain Weatherston		Title Consultant to LoradoChem		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant to LoradoChem Inc.			
4. Typed Name Iain Weatherston		5. Date May 27, 2013			

TRANSMITTAL DOCUMENT

NAME & ADDRESS OF APPLICANT

LoradoChem Inc., 1020 Stony Hill Road, Suite 200, Yardley, PA 19067

REGULATORY ACTION IN SUPPORT OF WHICH THIS APPLICATION IS SUBMITTED

Application to Register LC-2012-2 Fipronil for Dogs
An Amendment

TRANSMITTAL DATE

May 27, 2013

LIST OF SUBMITTED MATERIAL

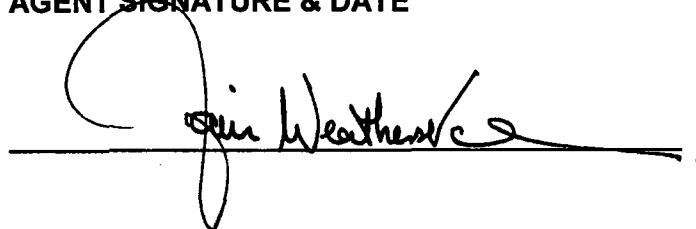
86230-2-A-1 Administrative Materials: Correspondence, Application & Label

COMPANY NAME

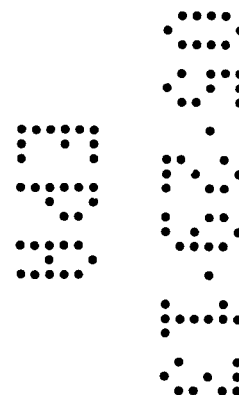
LoradoChem Inc., 1020 Stony Hill Road, Suite 200, Yardley, PA 19067

COMPANY CONTACT/AGENT

Dr. Iain Weatherston, J&T Associates LLC, 4061 North 156th Drive, Goodyear, AZ 85395

AGENT SIGNATURE & DATEA handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line.

May 27, 2013



**APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE**

AN AMENDMENT

End-Use Product
EPA Registration No. 86230-2

VOLUME 86230-2-A-1
ADMINISTRATIVE MATERIALS: CORRESPONDENCE, APPLICATION & LABEL

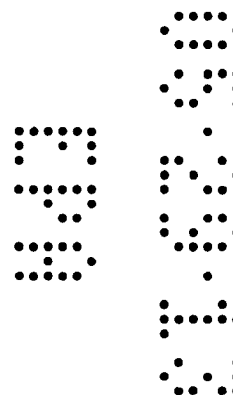
DATA REQUIREMENTS
40 CFR 152.10 & 156.10

AUTHOR
Iain Weatherston, Ph.D.

DATE COMPLETED
May 27, 2013

SPONSOR
LoradoChem Inc.
1020 Stony Hill Road, Suite 200, Yardley, PA 19067

SUBMITTED BY
J & T Associates LLC.
4061 North 156th Drive, Goodyear, AZ 85395



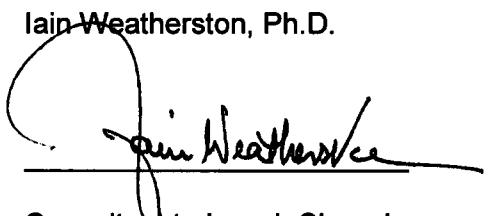
CONFIDENTIALITY CLAIMS**STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS**

NO claim of data confidentiality is made for information contained in this volume on the basis of its falling within the scope of FIFRA § 10 (d) (1) [A], [B] or [C].

COMPANY: LoardoChem Inc.

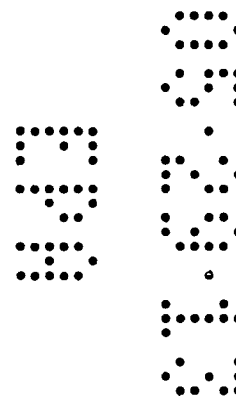
AGENT: ~~Iain Weatherston~~, Ph.D.

AGENT SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line.

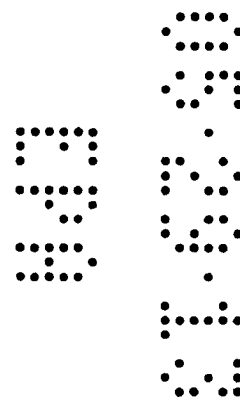
TITLE: Consultant to LoradoChem Inc.

DATE: May 27, 2013



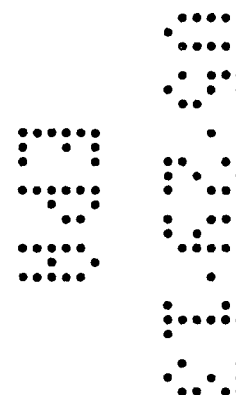
GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report **DO NOT FALL UNDER** the requirements of 40 CFR 160.



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J&T Associates LLC

Iain Weatherston Ph.D.

Director

623-217-9013 / 623-535-4055

E-mail: iweatherston@cox.net

May 27, 2013

Richard Gebken [PM#10]

U.S. EPA – OCSPP – OPP – RD – IB

One Potomac Yard (Room S-4900)

2777 South Crystal Drive,

Arlington, VA 22202-4501

SUBJECT: Application to register LC-2010-2 Fipronil for Dogs, an insecticide to control fleas, ticks and chewing lice. An Amendment.

COMPANY: LoradoChem Inc., 1020 Stony Hill Road, Suite 200, Yardley, PA 19067.

CONTACT: Iain Weatherston, Ph.D., J&T Associates LLC, 4061 North 156th Drive, Goodyear, AZ 85395. Contact information as per letterhead.

PRODUCT: LC-2010-2 Fipronil for Dogs [EPA Reg. No. 86230-2].

Dear Mr. Gebken:

As agent for, and on behalf of LoradoChem Inc., I am submitting for your review and approval this fast track amendment, allowing for (1) the manufacture of LC-2010-2 Fipronil for Dogs to be transferred to the Sergeant's Pet Care Products, Inc., facility in Omaha [EPA Establishment No. 2517-NE-02]. Once the date of the first manufacture at the Omaha facility is known it will be communicated to you, and (2) changes to the label of the subject product.

This amendment application is the first of three actions to be filed within the next two months which will impact the registration of this particular product. In addition to this amendment, the other two actions will be (a) a notification of an alternate source of the active ingredient fipronil, and (b) an alternate formulation to insert back into the formulation [REDACTED] which, although in the original approved product formulation, were removed [REDACTED] when the manufacturing was moved to Germany. This will be fully explained in the alternate formulation amendment package.

These actions follow on from discussions that took place at the meeting with you, Kaitlin Keller and Rosalind Gross on Thursday May 16, 2013 and also attended by Dave Petrick (Velcera) and Kelly Hoskins and Joe Conti of (Sergeant's).

As to the current amendment application, and to recap from my April 8 letter and our May 16 discussions:

1. Perrigo Company, last year, acquired Seargeant's Pet Care Products Inc., and then in 2013 acquired Velcera Inc., (parent to LoradoChem Inc., and FidoPharm Inc.). This necessitates some integration and consolidation within the companies.
2. LoradoChem Inc., intends to manufacture the subject product at the Sergeant's registered pesticide producing establishment in Omaha. At this time the current manufacturing site in Germany will be retained. Advance notice of the start of production in Omaha will be given to EPA prior to any product being produced and packaged there.
3. The manufacturing process of the subject product will remain that which was approved by the Agency during the registration.

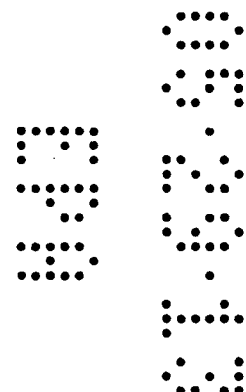
Manufacturing process information may be entitled to confidential treatment

4. The packaging of the product in Omaha will be changed to approved, child resistant packaging currently used by Sergeant's in their fipronil products that have the same dose volume. Please find following this letter (a) a letter of authorization from Sergeant's for the LoradoChem use of the detailed CRP data in support of the packaging change, and (b) a letter of certification that the packaging used for the LC-2010-2 Fipronil for Dogs product to be manufactured for LoradoChem by Sergeant's in their Omaha facility meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700, 15(b) when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).
5. The label for the subject product is the same as the current stamped approved label with two exceptions, (a) the change in packaging necessitates a change in the instructions for opening the tube/vial in order to apply the product to the animal; (b) the submitted draft labels have also been updated to include the "mitigation" language detailed in the Lois Rossi letter of September 2011. This application contains one copy of a "clean label" and one copy of a redline copy to facilitate the tracking of the changes.

Should you require further information or have any questions, please do not hesitate to contact me by phone or e-mail.

Sincerely,


Iain Weatherston, Ph.D.





Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138-3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 16, 2013

Richard Gebken (PM 10)
 Document Processing Desk
 Office of Pesticide Programs (7504P)
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 S. Crystal Drive
 Arlington, VA 22202

Subject: Letter of Authorization
 LC-2010-1 Fipronil for Cats, EPA Reg. No. 86230-1
 LC-2010-2 Fipronil for Dogs, EPA Reg. No. 86230-2

Dear Mr. Gebken:

This letter is to notify the U.S. Environmental Protection Agency that Sergeant's Pet Care Products, Inc. (Sergeant's, EPA Company Number 2517) authorizes Loradochem, Inc. (1020 Stony Hill Road, Suite 200, Yardley PA 19067, EPA Company Number 86230) to cite child resistant packaging (CRP) data in support of its amendments to the registrations of the above referenced products. These CRP data are proprietary to Sergeant's and this letter does not confer ownership, exclusive rights of the data or rights to obtain copies of the data; other companies may rely on these data if authorized by Sergeant's. Below is a list of the CRP studies and MRID Numbers that Loradochem is authorized to cite.

Citation	MRID Number
Hoskins, K. (2011) Use of One Tube 1x Child Resistant Unit Packaging Data (Child and Senior) to Support All Unit Configurations for Fipronil Based Spot-On Registrations. Project Number: SERGEANT/S/02/09/11.	48614201
Ward, R. (2011) Evaluation of the Dog Squeeze On 0.67ml White Applicator with Orange Label Indicator (1x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc. Project Number: 1746/008.	48614202
Ward, R. (2011) Evaluation of the Dog Squeeze On 1.34ml White Applicator with Green Label Indicator (1x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc: Final Report. Project Number: 1746/009.	48614203
Ward, R. (2011) Evaluation of the Dog Squeeze on 2.68ml White Applicator with Red Label Indicator (1x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Product, Inc: Final Report. Project Number: 1746/010.	48614204
Ward, R. (2011) Evaluation of the Dog Squeeze On 4.02ml White Applicator with Blue Label Indicator (1x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc: Final Report. Project Number: 1746/011	48614205
Ward, R. (2010) Evaluation of the Cat Squeeze on 0.5ml White Applicator with	48059503

Richard Gebken


Page 2

April 16, 2013

Citation	MRID Number
Purple Label Indicator (3x), Scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc. Project Number: 1746/001.	
Ward, R. (2010) Evaluation of the Dog Squeeze on 0.67ml White Applicator with Orange Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/002	48059803
Ward, R. (2010) Evaluation of the Dog Squeeze on 1.34ml White Applicator with Green Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/003	48059804
Ward, R. (2010) Evaluation of the Dog Squeeze on 2.68ml White Applicator with Red Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/004	48059805
Ward, R. (2010) Evaluation of the Dog Squeeze on 4.02ml White Applicator with Blue Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/005.	48059806
Ward, R. (2010) Evaluation of the Cat Squeeze on 0.5mL White Applicator with Purple Label Indicator (3x), Scissors to Open - F= 1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Amended Final Report. Project Number: 1746/001.	48279601
Ward, R. (2011) Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (1x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/007.	48613701
Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label indicator (3x), scissors to open - F=1 as a poison prevention Package for Sergeants Pet Care Products, Inc. Perritt Study No. 1746-006	48650101

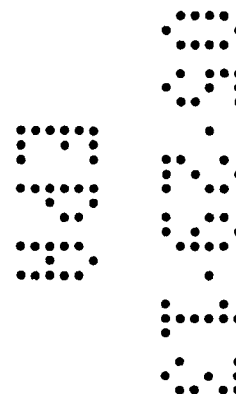
Please feel free to contact me with any questions via telephone at 402-938-7079 or via email at KHoskins@SERGEANTS.com.

Sincerely,



Kelly Hoskins
Director of Regulatory Affairs

cc: David Petrick, Velcera, Inc.



J&T Associates LLC

Iain Weatherston Ph.D.
Director
623-217-9013 / 623-535-4055
E-mail: iweatherston@cox.net

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

May 27, 2013

Subject: Child Resistant Packaging Certification
LC-2010-2 Fipronil for Dogs (EPA Reg. No. 86230-2)

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995):

- LC-2010-2 Fipronil for Dogs (EPA Reg. No. 86230-2)

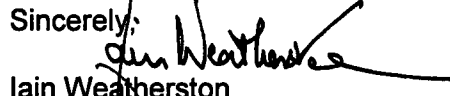
Loradochem, Inc. (Loradochem, 1020 Stony Hill Road, Suite 200, Yeardley, PA 19067, EPA Company Number 86230), is submitting this child resistant packaging certification statement to support the EPA registered products listed above. This certification statement is based on data submitted to EPA by Sergeant's Pet Care Products, Inc. for their child resistant packaging.

The data to support CRP packaging by Sergeant's Pet Care Products, Inc. are found under MRID 48614202, 48614203, 48614204, 48614205, 48059803, 48059804, 48059805 and 48059806. These data allow for CRP packaging configurations of 1X, 2X, 3X, 4X, 5X, 6X, 12X, and 24X in the fill weights 0.023 fl. oz. (0.67 ml), 0.045 fl. oz. (1.34 ml), 0.091 fl. oz. (2.68 ml), and 0.136 fl. oz. (4.02 ml). The CRP instructions for the Sergeant's Pet Care Product's, Inc. packaging is "How to Open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line."

Please note that Loradochem certifies that the packaging and colors used for the product LC-2010-2 Fipronil for Dogs (EPA Reg. No. 86230-2) is the same, 100% identical, as tested and approved by EPA, as Sergeant's Pet Care Products, Inc. (such as EPA Reg. Nos. 2517-134, 2517-136, 2517-140, 2517-141, 2517-142, 2517-143, 2517-149, 2517-150, and 2517-151) for their child resistant packaging, because it will be packaged at Sergeant's Pet Care Products, Inc.

If you have any questions or need additional information, please contact me at iweatherston@cox.net or by phone at 623-535-4055.

Sincerely,


Iain Weatherston
Consultant to LoradoChem Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 LoradoChem Inc., 1020 Stony Mill Road, Suite 200, Yardley PA 19067 (Agent 623-535-4055)

EPA Registration Number/File Symbol
 86230-2

Active Ingredient(s) and/or representative test compound(s)
 Fipronil

Date
 May 27, 2013

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 INDOOR

Product Name
 LC-2010-2 Fipronil for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Iain Weatherston

Date

05-27-2013

Typed or Printed Name and Title

Iain Weatherston, Ph.D. Consultant/Agent

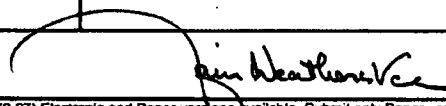


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/27/2013		EPA Reg No./File Symbol 86230-2		Page 1 of 4	
Applicant's/Registrant's Name & Address LoradoChem Inc. 2010 Stony Hill Road, Suite 200, Yardley PA 19067 (Agent 623-535-4055)		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	PRODUCT IDENTITY AND COMPOSITION	48013001	LORADOCEM INC.	OWN	
		48319701	LORADOCEM INC	OWN	
830.1600	DESCRIPTION OF STARTING MATERIALS	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
830.1650	FORMULATION PROCESS	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
830.1750	CERTIFIED LIMITS		LORADOCEM INC	OWN	see CSF
830.1800	ENFORCEMENT ANALYTICAL METHOD	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
830.6302	COLOR	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
830.6303	PHYSICAL STATE	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
830.6304	ODOR	48013001	LORADOCEM INC	OWN	
		48319701	LORADOCEM INC	OWN	
Signature 			Name and Title Iain Weatherston Consultant/Agent to LoradoChem Inc.		Date 05/27/2013

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Agency Internal Use Copy

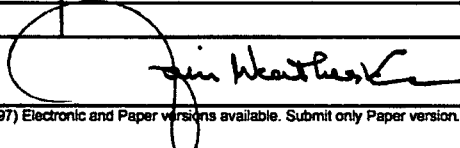


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/27/2013		EPA Reg No./File Symbol 86230-2		Page 2 of 4	
Applicant's/Registrant's Name & Address LoradoChem Inc. 2010 Stony Hill Road, Suite 200, Yardley PA 19087 (Agent 623-535-4055)		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	OXIDATION REDUCTION POTENTIAL	48013001	LORADOCHEM INC.	OWN	
		48319701	LORADOCHEM INC	OWN	
830.6315	FLAMMABILITY	48013001	LORADOCHEM INC	OWN	
		48319701	LORADOCHEM INC	OWN	
830.6316	EXPLODABILITY	48013001	LORADOCHEM INC	OWN	
		48319701	LORADOCHEM INC	OWN	
830.6317	STORAGE STABILITY		LORADOCHEM INC	OWN	in progress
830.6319	MISCIBILITY				not required
830.6320	CORROSION CHARACTERISTICS		LORADOCHEM INC	OWN	in progress
830.6321	DIELECTRIC BREAKDOWN CONSTANT				not required
830.7000	pH	48319701	LORADOCHEM INC	OWN	
		48013001	LORADOCHEM INC	OWN	
830.7050	UV/VISIBLE ABSORPTION				not required
830.7100	VISCOSITY	48013001	LORADOCHEM INC	OWN	
		48319701	LORADOCHEM INC	OWN	
Signature 			Name and Title Iain Weatherston Consultant/Agent to LoradoChem Inc.		Date 05/27/2013

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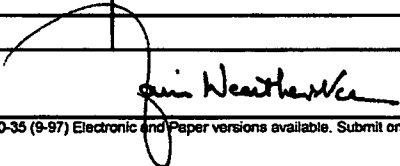


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DATA MATRIX

Date 5/27/2013		EPA Reg No./File Symbol 86230-2		Page 3 of 4	
Applicant's/Registrant's Name & Address LoradoChem Inc. 2010 Stony Hill Road, Suite 200, Yardley PA 19067 (Agent 623-535-4055)		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	MELTING POINT RANGE				not required
830.7220	BOILING POINT RANGE				not required
830.7300	DENSITY, BULK DENSITY, SPECIFIC GRAVITY	48013001	LORADOCHEM INC	OWN	
		48319701	LORADOCHEM INC	OWN	
830.7373	DISSOCIATION CONSTANT				not required
830.7550/60/70	PARTITION COEFFICIENT				not required
830.7840/50	WATER SOLUBILITY				not required
830.7850	VAPOR PRESSURE				not required
NON-GUIDELINE	CHILD RESISTANT PACKAGING DATA	48614201	SERGEANT'S	EXC	
		48614202		EXC	
		48614203		EXC	
		48614204		EXC	
		48614205		EXC	
		48059803		EXC	
		48059804		EXC	
Signature 			Name and Title Iain Weatherston Consultant/Agent to LoradoChem Inc.		Date 05/27/2013

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Agency Internal Use Copy



Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 5/27/2013

EPA Reg No./File Symbol 86230-2

Page 4 of 4

Applicant's/Registrant's Name & Address

LoradoChem Inc. 2010 Stony Hill Road, Suite 200, Yardley PA 19067 (Agent 623-535-4055)

Product

LC-2010-2 Fipronil for Dogs

Ingredient	Fipronil
------------	----------

[illegible]

Signature

Name and Title

Iain Weatherston Consultant/Agent to LoradoChem Inc.

Date _____

05/27/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 31, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

IAIN WEATHERSTON, PH.D.
J&T ACCOCIATES LLC
LORADOCHEM, INC.
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85395-

PRODUCT NAME: LC-2010-2 FIPRONIL FOR DOGS
COMPANY NAME: LORADOCHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86230-2
EPA RECEIPT DATE: 05/29/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in cursive script, appearing to read "Julie Vise".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: DMCOP

Date: 4/3/13

PM #: 10

EPA Reg. Number: <u>86230-2</u>		EPA Receipt Date: <u>5/29/13</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?		✓	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?	✓		
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)	✓		
	a) Electronic Label submitted?			
Comments: CRP extraction Label amendment				

Receipt for Section 3



S: 938107

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 86230 LORADOCEM, INC.



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 10

Product #: 86230-2 Product Name: LC-2010-2 FIPRONIL FOR DOGS

Override#:

Me Too Section3: 85331-3

Me Too Product Name: FRONTLINE TOP SPOT FOR DOGS

Application Date: 27-May-2013

OPP Rec'd Date: 29-May-2013

Front End Date: 30-May-2013

Risk Manager Send Date: 30-May-2013

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Receipt Content	Des
Paper Label	

View/Edit

CRP action
Label Amendment.

W

Fee for Service

{936107#~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. **10**

Receipt No.

S- **936107**

EPA File Symbol/Reg. No.

86230-2

Pin-Punch Date:

5/29/2013



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

Date: 5/30/13

Remarks:

CRP ~~Grant~~ Citation Authorization

Material Sent for Data Extraction

Reg. # 86230-2

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification Dated 1/16/12

☐ New CSF(s) Dated 1/16/12

☐ Other: _____

☐ Decision #: D-460123

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: M. Masterton

305-5335
Phone: _____ Division: RD

Date: 4/12/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 12, 2012

Ian Weatherston, Ph.D.
Agent for: LoroadoChem Inc.
J&T Associates
4061 North 156th Drive
Goodyear, AZ 85395

Subject: Minor Formulation Amendment
LC-2010-1 Fipronil for Dogs
EPA Reg. No. 86230-2
Basic Formulations

Dear Dr. Weatherston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 1/16/12 for **EPA Registration 86230-2**. The Registration Division (RD) has conducted a review of the Confidential Statement of Formula (CSF) submitted with this request for its applicability under PRN 98-10 and finds that the change(s) requested falls within the scope of PRN 98-10. Therefore, the revised Basic Formulation CSF dated 1/16/2012 is **acceptable**. A copy of the CSF has been added to the registration file for the subject product.

If you have any questions, please contact me via telephone at 703-305-5335 or e-mail (mastradone.paul@epa.gov).

Sincerely,

Paul Mastradone, Ph.D.
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)
Office of Pesticide Programs

J&T Associates LLC

Iain Weatherston Ph.D.
Director
623-217-9013 / 623-535-4055
E-mail: iweatherston@cox.net

Minor Formulation Review Coordinator
Registration Support Branch [Minor Formulation Amendment]
U.S. EPA – OPP – RD
Document Processing Desk
One Potomac Yard,
2777 South Crystal Drive,
Arlington VA 22202.

January 16th 2012

SUBJECT: Two minor formulation amendments as per PRN 98-10 Section V A(3)
COMPANY: LoradoChem Inc., 2929 Arch Street, Circa Centre 12th Floor, Philadelphia, PA 19104.
CONTACT: Dr. Iain Weatherston, J&T Associates LLC., 4061 North 156th Drive, Goodyear, AZ 85395.
[contact information as per letterhead].
PRODUCTS: LC-2010-1 Fipronil for Cats [86230-1]
LC-2010-2 Fipronil for Dogs [86230-2]

Dear Coordinator:

As agent for, and on behalf of LoradoChem Inc., I am filing for your review and approval two Minor Formulation Amendments (MFA) for the subject products. In both cases some inert materials

have been removed and replaced with one of the already approved inerts, namely [REDACTED] This will then bring the formulations of these two products into line with the formulations of the sister products, LC-2010-3 Fipronil Plus S-Methoprene for Cats [85495-1] formerly [86230-3] and LC-2010-4 Fipronil Plus S-Methoprene for Dogs [85495-2] formerly [86230-4.]

The MFA's for the Fipronil plus S-methoprene products were submitted on August 31, 2011 and approved September 20, 2011. LoradoChem wishes to ensure a smooth simultaneous transition at both manufacturing facilities and certifies that no product made to the specifications of the current CSF's (dated August 4, 2011) will be manufactured after February 20th 2012.

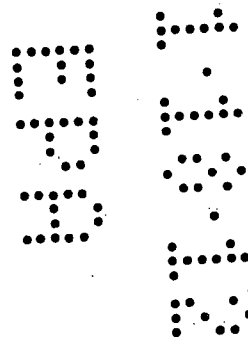
As per PRN 98-10, please find attached for each product, a completed pesticide application form [Form 8570-1], one copy of the current CSF and two copies of the new CSF.

In order to expedite approval, if there are any questions or further information is required please do not hesitate to contact me by e-mail or telephone.

Sincerely,


Iain Weatherston
Agent for LoradoChem Inc.

cc: Richard Gebken [OPP-RD-IB]
Dr. David Petrick [Velcera Inc.]
Stanley Abramson [Arent Fox]



Inert ingredient information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. /LC-2010-1 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., 2929 Arch Street, Circa Centre 12th Floor, Philadelphia, PA 19104 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Minor formulation amendment as per PRN 98-10

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)					
Name IAIN WEATHERSTON		Title Consultant, Agent to LoradoChem Inc.		Telephone No. (Include Area Code) 623-535-4055	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant, Agent to LoradoChem Inc.			
4. Typed Name IAIN WEATHERSTON		5. Date January 16, 2012			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 14, 2011

Iain Weatherston, PhD
(Agent for LoradoChem, Inc.)
J & T Associates
4061 North 156th Drive
Goodyear, AZ 85395

Subject: Revise basic Confidential Statement of Formula (CSF) to "add new site for manufacture."

LC-2010-1 Fipronil for Cats: EPA Reg. No. 86230-1
LC-2010-2 Fipronil for Dogs: EPA Reg. No. 86230-2
LC-2010-3 Fipronil & S-Methoprene for Cats: EPA Reg. No. 86230-3 (85495-1)
LC-2010-4 Fipronil & S-Methoprene for Dogs: EPA Reg. No. 86230-4 (85495-2)

Submissions dated August 04, 2011

Dear Dr. Weatherston:

The above referenced labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

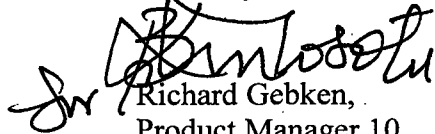
For each of the subject products, the revised accepted basic CSF dated 08/04/11 supersedes that of 06/29/2010, and all previously accepted ones. We have included copies of the revised CSF in the records for the products.

In the labeling for each product, replace "Inert Ingredients" with "***Other Ingredients***"

Please note that we have approved the amended labeling for the subject products with the understanding that the labels are consistent with the Agency's previously stamped accepted ones; and other than the above stated revisions, no other changes have been made to the labeling and/or the CSF.

For your records, you have been sent (via email) copies of our reviews (CRP and Prod. Chem.). Also, see enclosed copy of the stamped label for each product. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken", written over the printed name.

Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel C: Labeling on the Child Resistant Package

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of dog)

thru **INERT INGREDIENTS.....90.3%**

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2

ACCEPTED
DEC 14 2011
**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**
EPA. Reg. No: 86230-2

Sublabel A: Box Label**[Front Panel of Box]**

LC-2010-2
 [Alternate Brand Names]
 [PetArmor™]
 [TrustGard™]
 [Velcera® Fipronil]

FOR DOGS

3 (Drawing of pipette)
 [Alternate Packaging]
 [6 (Drawing of pipette)]
 [1 (Drawing of pipette)]
 Pipette[s]

Kills fleas, ticks, chewing lice & Mosquitoes

- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of dog)

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN**CAUTION**

[Contains 3-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 3-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 3-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 6-0.023 fl.oz (0.67 mL) pipettes]

Or

[Contains 6-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 6-0.091 fl.oz. (2.68 mL) pipettes]

Or

[Contains 6-0.136 fl.oz (4.02 mL) pipettes]

Or

[Contains 1-0.023 fl.oz (0.67 mL) pipette]

Or

[Contains 1-0.045 fl.oz. (1.34 mL) pipette]

Or

[Contains 1-0.091 fl.oz. (2.68 mL) pipette]

Or

[Contains 1-0.136 fl.oz (4.02 mL) pipette]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Compare to Frontline® Top Spot same active ingredient*

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing up to 22 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 23-44 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 45-88 lbs.]

Or ... [ONLY on dogs weighing 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

LoradoChem, Inc.
Circa Center, 12th Floor
2929 Arch Street
Philadelphia, PA 18104-2891 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

©2011 LoradoChem, Inc. All rights reserved.

(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in XXXXX

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	
Or	
[Only use on dogs 89-132 lbs.]	

[Label identifiers that will be used to identify each respective package size contained within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	
Or	
[Only use on dogs 89-132 lbs.]	
[Label identifiers that will be used to identify each respective package size contained within the box.]	

[Left side panel of Box]

Lot Number:	3 (Drawing of pipette)
	[6 (Drawing of pipette)]
	[1 (Drawing of pipette)]
	Pipette[s]

Sublabel B: Package Insert**LC-2010-2** [or other approved alternate brand name] For Dogs**Only for use on dogs and puppies 8 weeks or older****LC-2010-2** [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.**ACTIVE INGREDIENT**

Fipronil.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN**CAUTION**

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, **LC-2010-2** [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. **LC-2010-2** [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, **LC-2010-2** [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. **READ ENTIRE LABEL AND**

ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * Up to 22 lbs.
- * 23 to 44 lbs.
- * 45 to 88 lbs.
- * 89 to 132 lbs.

Warranty

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

* This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

LoradoChem, Inc.
Circa Center, 12th Floor
2929 Arch Street
Philadelphia, PA 18104-2891 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in XXXXXX

Sublabel C: Labeling on the Child Resistant Package

Top of lidding foil: Dotted line with representation of a scissors

Company Name: LoradoChem

Product Name: LC-2010-2 [or other approved alternate brand name] For Dogs

Graphic picture of the pipette

Instructions: **To Open Package:**
Cut across the top
as shown.
Peel down the foil
completely before
removing pipette.

Species and amount: [Dogs up to 22 lbs. – 0.023 fl.oz.]
Or
[Dogs 23-44 lbs. – 0.045 fl.oz.]
Or
[Dogs 45-88 lbs. – 0.091 fl.oz.]
Or
[Dogs 89-132 lbs. – 0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Lot number: Lot No: XXXX

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.7%)

Body of pipette: **LoradoChem**
 [0.023 fl.oz.]
 Or
 [0.0045 fl.oz.]
 Or
 [0.091 fl.oz.]
 Or
 [0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name] For
 Dogs

[For Dogs up to 22 lbs.]

Or

[For Dogs 23-44 lbs.]

Or

[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

KEEP OUT OF REACH OF CHILDREN
CAUTION

See package insert for directions for use.

EPA Reg. No. 86230-2

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 [or other approved alternate brand name] For Dogs Care Card

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw

Date of Application

Month 2

Drawing of paw

Date of Application

Month 3

Drawing of paw

Date of Application

[Month 4

Drawing of paw

Date of Application

Month 5

Drawing of paw

Date of Application

Month 6

Drawing of paw

Date of Application

]

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name:

lbs.

